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CODE OF FEDERAL REGULATIONS

Title 42
Public Health

Parts 414 to 429

Revised as of October 1, 2012

Containing a codification of documents
of general applicability and future effect

As of October 1, 2012

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To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 414.1 *refers to title 42, part 414, section 1.*

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Title 17 through Title 27.....as of April 1
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Title 42 through Title 50.....as of October 1

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CHARLES A. BARTH,
Director,
Office of the Federal Register.
October 1, 2012.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–413, parts 414–429, parts 430 to 481, and part 482 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second, third, and fourth volumes (parts 400–413, parts 414–429, and parts 430 to 481) include regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the fifth volume (part 482 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2012.

For this volume, Robert J. Sheehan, III was Chief Editor. The Code of Federal Regulations publication program is under the direction of Michael L. White, assisted by Ann Worley.

Title 42—Public Health

(This book contains parts 414 to 429)

Part

CHAPTER IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services (Continued) 414

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 62 FR 46037, Aug. 29, 1997; 66 FR 39452, July 31, 2001; and 67 FR 36540, May 24, 2002.

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AUTHORITY: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

SOURCE: 55 FR 23441, June 8, 1990, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 414 appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

Subpart A—General Provisions

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l)—Establishment of a fee schedule for ambulance services.

1834(m)—Rules for Medicare reimbursement for telehealth services.

1842(o)—Rules for payment of certain drugs and biologicals.

1847(a) and (b)—Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

1848—Fee schedule for physician services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

[67 FR 9132, Feb. 27, 2002, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 48409, Aug. 18, 2006]

§ 414.2 Definitions.

As used in this part, unless the context indicates otherwise—

AA stands for anesthesiologist assistant.

AHPB stands for adjusted historical payment basis.

CF stands for conversion factor.

CRNA stands for certified registered nurse anesthetist.

CY stands for calendar year.

FY stands for fiscal year.

GAF stands for geographic adjustment factor.

GPCI stands for geographic practice cost index.

HCPCS stands for CMS Common Procedure Coding System.

Health Professional Shortage Area (HPSA) means an area designated under section 332(a)(1)(A) of the Public Health Service Act as identified by the Secretary prior to the beginning of such year.

Major surgical procedure means a surgical procedure for which a 10-day or 90-day global period is used for payment under the physician fee schedule and section 1848(b) of the Act.

Physician services means the following services to the extent that they are covered by Medicare:

(1) Professional services of doctors of medicine and osteopathy (including osteopathic practitioners), doctors of optometry, doctors of podiatry, doctors of dental surgery and dental medicine, and chiropractors.

(2) Supplies and services covered ''incident to'' physician services (excluding drugs as specified in § 414.36).

(3) Outpatient physical and occupational therapy services if furnished by a person or an entity that is not a Medicare provider of services as defined in § 400.202 of this chapter.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding diagnostic laboratory tests paid under the fee schedule established under section 1833(h) of the Act).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens, as described in section 1861(s)(2)(G) of the Act.

(7) Bone mass measurement.

RVU stands for relative value unit.

(8) Screening mammography services.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994; 60 FR 63177, Dec. 8, 1995; 63 FR 34328, June 24, 1998; 66 FR 55322, Nov. 1, 2001; 75 FR 73616, Nov. 29, 2010]

§ 414.4 Fee schedule areas.

(a) *General.* CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes.* CMS announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

Subpart B—Physicians and Other Practitioners

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

§ 414.20 Formula for computing fee schedule amounts.

(a) *Participating supplier.* The fee schedule amount for a participating supplier for a physician service as defined in § 414.2 is computed as the product of the following amounts:

(1) The RVUs for the service.

(2) The GAF for the fee schedule area.

(3) The CF.

(b) *Nonparticipating supplier.* The fee schedule amount for a nonparticipating supplier for a physician service as defined in § 414.2 is 95 percent of the fee schedule amount as calculated in paragraph (a) of this section.

[62 FR 59101, Oct. 31, 1997]

§ 414.21 Medicare payment basis.

Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.

[62 FR 59101, Oct. 31, 1997]

§ 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

(a) *Physician work RVUs*—(1) *General rule.* Physician work RVUs are established using a relative value scale in which the value of physician work for a particular service is rated relative to the value of work for other physician services.

(2) *Special RVUs for anesthesia and radiology services)*—(i) *Anesthesia services.* The rules for determining RVUs for anesthesia services are set forth in § 414.46.

(ii) *Radiology services.* CMS bases the RVUs for all radiology services on the relative value scale developed under section 1834(b)(1)(A) of the Act, with appropriate modifications to ensure that the RVUs established for radiology services that are similar or related to other physician services are consistent with the RVUs established for those similar or related services.

(b) *Practice expense RVUs.* (1) Practice expense RVUs are computed for each service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average practice expense percentage for a service or class of services is computed as follows:

(i) Multiply the average practice expense percentage for each specialty by the proportion of a particular service or class of service performed by that specialty.

(ii) Add the products for all specialties.

(3) For services furnished beginning calendar year (CY) 1994, for which 1994 practice expense RVUs exceed 1994 work RVUs and that are performed in office settings less than 75 percent of the time, the 1994, 1995, and 1996 practice expense RVUs are reduced by 25 percent of the amount by which they exceed the number of 1994 work RVUs. Practice expense RVUs are not reduced to less than 128 percent of 1994 work RVUs.

(4) For services furnished beginning January 1, 1998, practice expense RVUs for certain services are reduced to 110 percent of the work RVUs for those services. The following two categories of services are excluded from this limitation:

(i) The service is provided more than 75 percent of the time in an office setting; or

(ii) The service is one described in section 1848(c)(2)(G)(v) of the Act, codified at 42 U.S.C. 1395w–4(c)(2)(G). Section 1848(c)(2)(G)(v) of the Act refers to the 1998 proposed resource-based practice expense RVUs (as specified in the June 18, 1997 physician fee schedule proposed rule (62 FR 33158)) for the specific site, either in-office or out-of-office, increased from its 1997 practice expense RVUs.)

(5) For services furnished beginning January 1, 1999, the practice expense RVUs are based on 75 percent of the practice expense RVUs applicable to services furnished in 1998 and 25 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2000, the practice expense RVUs are based on 50 percent of the practice expense RVUs applicable to services furnished in 1998 and 50 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2001, the practice expense RVUs are based on 25 percent of the

practice expense RVUs applicable to services furnished in 1998 and 75 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5).

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

(ii) Only one practice expense RVU per code can be applied for each of the following services: services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits, that are furnished exclusively in one setting; and major surgical services.

(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by March 1, 2004 to determine CY 2005 practice expense RVUs and by March 1, 2005 to determine CY 2006 practice expense RVUs.

(c) *Malpractice insurance RVUs.* (1) Malpractice insurance RVUs are computed for each service or class of services by applying average malpractice insurance historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average historical malpractice insurance percentage for a service or class of services is computed as follows:

(i) Multiply the average malpractice insurance percentage for each specialty by the proportion of a particular service or class of services performed by that specialty.

(ii) Add all the products for all the specialties.

(3) For services furnished in the year 2000 and subsequent years, the malpractice RVUs are based on the relative malpractice insurance resources.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 62 FR 59102, Oct. 31, 1997; 63 FR 58910, Nov. 2, 1998; 64 FR 59441, Nov. 2, 1999; 65 FR 25668, May 3, 2000; 65 FR 65440, Nov. 1, 2000; 67 43558, June 28, 2002; 68 FR 63261, Nov. 7, 2003; 72 FR 66932, Nov. 27, 2007; 73 FR 69935, Nov. 19, 2008; 76 FR 73471, Nov. 28, 2011]

§ 414.24 Review, revision, and addition of RVUs for physician services.

(a) *Interim values for new and revised HCPCS level 1 and level 2 codes.* (1) CMS establishes interim RVUs for new services and for codes for which definitions have changed.

(2) CMS publishes a notice in the FEDERAL REGISTER to announce interim RVUs and seek public comment on them. The RVUs are effective prospectively for services furnished beginning on the effective date specified in the notice.

(3) After considering public comments, CMS revises, if necessary, the interim RVUs and announces those revisions in a final notice published in the FEDERAL REGISTER. Any revisions in the RVUs are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(b) *Revision of RVUs for established HCPCS level 1 and level 2 codes.* (1) CMS publishes a proposed notice in the FEDERAL REGISTER to announce changes in RVUs for established codes and provides an opportunity for public comment no less often than every 5 years.

(2) After considering public comments, CMS publishes a final notice in the FEDERAL REGISTER to announce revisions to RVUs.

(3) The RVU revisions are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(c) *Values for local codes (HCPCS Level 3).* (1) Carriers establish relative values for local codes for services not included in HCPCS levels 1 or 2.

(2) Carriers must obtain prior approval from CMS to establish local codes for services that meet the definition of ''physician services'' in § 414.2.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992]

§ 414.26 Determining the GAF.

CMS establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* CMS uses the following indices to establish the GAF:

(1) An index that reflects one-fourth of the difference between the relative value of physicians' work effort in each of the different fee schedule areas as determined under § 414.22(a) and the national average of that work effort.

(2) An index that reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in each of the different fee schedule areas as determined under § 414.22(b) compared to the national average of those costs.

(3) An index that reflects the relative costs of malpractice expenses in each of the different fee schedule areas as determined under § 414.22(c) compared to the national average of those costs.

(b) *Class-specific practice cost indices.* If the application of a single index to different classes of services would be substantially inequitable because of differences in the mix of goods and services comprising practice expenses for the different classes of services, more than one index may be established under paragraph (a)(2) of this section.

(c) *Adjusting the practice expense index to account for the Frontier State floor—* (1) *General criteria.* Effective on or after January 1, 2011, CMS will adjust the practice expense index for physicians' services furnished in qualifying States to recognize the practice expense index floor established for Frontier States. A qualifying State must meet the following criteria:

(i) At least 50 percent of counties located within the State have a population density less than 6 persons per square mile.

(ii) The State does not receive a nonlabor related share adjustment determined by the Secretary to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(2) *Amount of adjustment.* The practice expense value applied for physicians' services furnished in a qualifying State will be not less than 1.00.

(3) *Process for determining adjustment.* (i) CMS will use the most recent population estimate data published by the U.S. Census Bureau to determine county definitions and population density. This analysis will be periodically revised, such as for updates to the decennial census data.

(ii) CMS will publish annually a listing of qualifying Frontier States receiving a practice expense index floor attributable to this provision.

(d) *Computation of GAF.* The GAF for each fee schedule area is the sum of the physicians' work adjustment factor, the practice expense adjustment factor, and the malpractice cost adjustment factor, as defined in this section:

(1) The geographic physicians' work adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the work component and the geographic physicians' work index value established under paragraph (a)(1) of this section.

(2) The geographic practice expense adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the practice expense component, multiplied by the geographic practice cost index (GPCI) value established under paragraph (a)(2) of this section.

(3) The geographic malpractice adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the malpractice component, multiplied by the GPCI value established under paragraph (a)(3) of this section.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 75 FR 73616, Nov. 29, 2010]

§ 414.28 Conversion factors.

CMS establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* CMS established the CF for 1992 so that had section 1848 of the Act applied during 1991, it would have resulted in the same aggregate amount of payments for physician services as the estimated aggregate amount of these payments in 1991, adjusted by the update for 1992 computed as specified in § 414.30.

(b) *Subsequent CFs.* For calendar years 1993 through 1995, the CF for each year is equal to the CF for the previous year, adjusted in accordance with § 414.30. Beginning January 1, 1996, the CF for each calendar year may be further adjusted so that adjustments to the fee schedule in accordance with section 1848(c)(2)(B)(ii) of the Act do not cause total expenditures under the fee schedule to differ by more than $20 million from the amount that would have been spent if these adjustments had not been made.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 53877, Oct. 18, 1995; 60 FR 63177, Dec. 8, 1995]

§ 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

(a) *General rule.* The CF update for a CY equals the Medicare Economic Index increased or decreased by the number of percentage points by which the percentage increase in expenditures for physician services (or for a particular category of physician services, such as surgical services) in the second preceding FY over the third preceding FY exceeds the performance standard rate of increase established for the second preceding FY.

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

(1) For CYs 1992 and 1993, 2 percentage points.

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points.

[55 FR 23441, June 8, 1990, as amended at 60 FR 63177, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§ 414.32 Determining payments for certain physicians' services furnished in facility settings.

(a) *Definition.* As used in this section, *facility settings* include the following facilities:

(1) Hospital outpatient departments, including clinics and emergency rooms.

(2) Hospital inpatient departments.

(3) Comprehensive outpatient rehabilitation facilities.

(4) Comprehensive inpatient rehabilitation facilities.

(5) Inpatient psychiatric facilities.

(6) Skilled nursing facilities.

(b) *General rule.* If physicians' services of the type routinely furnished in physicians' offices are furnished in facility settings before January 1, 1999, the physician fee schedule amount for those services is determined by reducing the practice expense RVUs for the services by 50 percent. For services furnished on or after January 1, 1999, the practice expense RVUs are determined in accordance with § 414.22(b)(5).

(c) *Services covered by the reduction.* CMS establishes a list of services routinely furnished in physicians' offices nationally. Services furnished at least 50 percent of the time in physicians' offices are subject to this reduction.

(d) *Services excluded from the reduction.* The reduction established under this section does not apply to the following:

(1) Rural health clinic services.

(2) Surgical services not on the ambulatory surgical center covered list of procedures published under § 416.65(c) of this chapter when furnished in an ambulatory surgical center.

(3) Anesthesiology services and diagnostic and therapeutic radiology services.

[58 FR 63687, Dec. 2, 1993, as amended at 60 FR 63177, Dec. 8, 1995; 62 FR 59102, Oct. 31, 1997; 63 FR 58911, Nov. 2, 1998; 64 FR 25457, May 12, 1999]

§ 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense, and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnished in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service if the following requirements are met:

(i) It is a procedure that can safely be furnished in the office setting in appropriate circumstances.

(ii) It requires specialized supplies that are not routinely available in physicians' offices and that are generally disposable.

(iii) It is furnished before January 1, 1999.

(3) For the purpose of paragraph (a)(2) of this section, provider settings include only the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(4) For the purpose of paragraph (a)(2) of this section, ''routinely furnished in provider settings'' means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) CMS establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.* Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.36 Payment for drugs incident to a physician's service.

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

(b) *Exception.* Separate payment is made under the following conditions for physician care plan oversight services furnished to beneficiaries who receive HHA and hospice services that are covered by Medicare:

(1) The care plan oversight services require recurrent physician supervision of therapy involving 30 or more minutes of the physician's time per month.

(2) Payment is made to only one physician per patient for services furnished during a calendar month period. The physician must have furnished a service requiring a face-to-face encounter with the patient at least once during the 6-month period before the month for which care plan oversight payment is first billed. The physician may not have a significant ownership interest in, or financial or contractual relationship with, the HHA in accordance with § 424.22(d) of this chapter. The physician may not be the medical director or employee of the hospice and may not furnish services under an arrangement with the hospice.

(3) If a physician furnishes care plan oversight services during a postoperative period, payment for care plan oversight services is made if the services are documented in the patient's medical record as unrelated to the surgery.

(c) *Special rules for payment of care plan oversight provided by nonphysician*

practitioners for beneficiaries who receive HHA services covered by Medicare. (1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) only if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either—

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995 as amended at 69 FR 66423, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 414.40 Coding and ancillary policies.

(a) *General rule.* CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* CMS establishes uniform national ancillary policies necessary to implement the fee schedule for physician services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery, bilateral surgery, split surgical global services, team surgery, and unusual services).

§ 414.42 Adjustment for first 4 years of practice.

(a) *General rule.* For services furnished during CYs 1992 and 1993, except as specified in paragraph (b) of this section, the fee schedule payment amount or prevailing charge must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), occupational therapists (OTs), and all other health care practitioners who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services or to services furnished in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The ''first year of practice'' is the first full CY during the first 6 months of which the physician, PT, OT, or other health care practitioner furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 6 months test.

(2) The ''second, third, and fourth years of practice'' are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment.* The fee schedule payment for the service of a new physician, PT, OT, or other health care practitioner is limited to the following percentages for each of the indicated years:

(1) First year—80 percent

(2) Second year—85 percent

(3) Third year—90 percent

(4) Fourth year—95 percent

[57 FR 42493, Sept. 15, 1992, as amended at 58 FR 63687, Dec. 2, 1993]

§ 414.44 Transition rules.

(a) *Adjusted historical payment basis—*(1) *All services other than radiology and nuclear medicine services.* For all physician services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by CMS without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services.* For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services.* For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101–239 and section 4102(g) of Public Law 101–508, adjusted by the update established for CY 1992.

(4) *Transition adjustment.* CMS adjusts the AHPB for all services by 5.5 percent to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physician services other than radiology services.* For physician services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(c) *Adjustment of 1992 payments for radiology services.* For radiology services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 109 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 109 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 9 percent of the fee schedule amount is substituted for the fee schedule amount.

(d) *Computation of payments for CY 1993.* For physician services subject to the transition rules in CY 1992 and furnished during CY 1993, the fee schedule is equal to 75 percent of the amount that would have been paid in the fee schedule area under the 1992 transition rules, adjusted by the amount of the 1993 update, plus 25 percent of the 1993 fee schedule amount.

(e) *Computation of payments for CY 1994.* For physician services subject to the transition rules in CY 1993, and furnished during CY 1994, the fee schedule is equal to 67 percent of the amount that would have been paid in the fee schedule area under the 1993 transition rules, adjusted by the amount of the 1994 update, plus 33 percent of the 1994 fee schedule amount.

(f) *Computation of payments for CY 1995.* For physician services subject to the transition rules in CY 1994 and furnished during CY 1995, the fee schedule is equal to 50 percent of the amount that would have been paid in the fee schedule area under the 1994 transition rules, adjusted by the amount of the 1995 update, plus 50 percent of the 1995 fee schedule amount.

§ 414.46 Additional rules for payment of anesthesia services.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Base unit* means the value for each anesthesia code that reflects all activities other than anesthesia time. These activities include usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services.

(2) *Anesthesia practitioner*, for the purpose of anesthesia time, means a physician who performs the anesthesia service alone, a CRNA who is not medically directed who performs the anesthesia service alone, or a medically directed CRNA.

(3) *Anesthesia time* means the time during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

(b) *Determinations of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, CMS pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The carrier bases the fee schedule amount for an anesthesia service on the product of the sum of allowable base and time units and an anesthesia-specific CF. The carrier calculates the time units from the anesthesia time reported by the anesthesia practitioner for the anesthesia procedure. The physician who fulfills the conditions for medical direction in § 415.110 (Conditions for payment: Anesthesiology services) reports the same anesthesia time as the medically-directed CRNA.

(2) CMS furnishes the carrier with the base units for each anesthesia procedure code. The base units are derived from the 1988 American Society of Anesthesiologists' Relative Value Guide except that the number of base units recognized for anesthesia services furnished during cataract or iridectomy surgery is four units.

(3) Modifier units are not allowed. Modifier units include additional units charged by a physician or a CRNA for patient health status, risk, age, or unusual circumstances.

(c) *Physician personally performs the anesthesia procedure.* (1) CMS considers an anesthesia service to be personally performed under any of the following circumstances:

(i) The physician performs the entire anesthesia service alone.

(ii) The physician establishes an attending physician relationship in one or two concurrent cases involving an intern or resident and the service was furnished before January 1, 1994.

(iii) The physician establishes an attending physician relationship in one case involving an intern or resident and the service was furnished on or after January 1, 1994 but prior to January 1, 1996. For services on or after January 1, 1996, the physician must be the teaching physician as defined in §§ 415.170 through 415.184 of this chapter.

(iv) The physician and the CRNA or AA are involved in a single case and the services of each are found to be medically necessary.

(v) The physician is continuously involved in a single case involving a student nurse anesthetist.

(vi) The physician is continuously involved in a single case involving a CRNA or AA and the service was furnished prior to January 1, 1998.

(2) CMS determines the fee schedule amount for an anesthesia service personally performed by a physician on the basis of an anesthesia-specific fee schedule CF and unreduced base units and anesthesia time units. One anesthesia time unit is equivalent to 15

minutes of anesthesia time, and fractions of a 15-minute period are recognized as fractions of an anesthesia time unit.

(d) *Anesthesia services medically directed by a physician.* (1) CMS considers an anesthesia service to be medically directed by a physician if:

(i) The physician performs the activities described in §415.110 of this chapter.

(ii) The physician directs qualified individuals involved in two, three, or four concurrent cases.

(iii) Medical direction can occur for a single case furnished on or after January 1, 1998 if the physician performs the activities described in §415.110 of this chapter and medically directs a single CRNA or AA.

(2) The rules for medical direction differ for certain time periods depending on the nature of the qualified individual who is directed by the physician.

(i) If more than two procedures are directed on or after January 1, 1994, the qualified individuals could be AAs, CRNAs, interns, or residents. The medical direction rules apply to student nurse anesthetists only if the physician directs two concurrent cases, each of which involves a student nurse anesthetist or the physician directs one case involving a student nurse anesthetist and the other involving a CRNA, AA, intern, or resident.

(ii) For services furnished on or after January 1, 2010, the medical direction rules do not apply to a single anesthesia resident case that is concurrent to another case which is paid under the medical direction payment rules as specified in paragraph (e) of this section.

(3) Payment for medical direction is based on a specific percentage of the payment allowance recognized for the anesthesia service personally performed by a physician alone. The following percentages apply for the years specified:

(i) CY 1994—60 percent of the payment allowance for personally performed procedures.

(ii) CY 1995—57.5 percent of the payment allowance for personally performed services.

(iii) CY 1996—55 percent of the payment allowance for personally performed services.

(iv) CY 1997—52.5 percent of the payment allowance for personally performed services.

(v) CY 1998 and thereafter—50 percent of the payment allowance for personally performed services.

(e) *Special payment rule for teaching anesthesiologist involved in a single resident case or two concurrent cases.* For physicians' services furnished on or after January 1, 2010, if the teaching anesthesiologist is involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount must be 100 percent of the fee schedule amount otherwise applicable if the anesthesia services were personally performed by the teaching anesthesiologist and the teaching anesthesiologist fulfilled the criteria in §415.178 of this chapter. This special payment rule also applies if the teaching anesthesiologist is involved in one resident case that is concurrent to another case paid under the medical direction payment rules.

(f) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, CMS bases the fee schedule amount on an anesthesia-specific CF and three base units. This represents payment for the physician's involvement in the pre-surgical anesthesia services.

(g) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) CMS allows separate payment under the fee schedule for certain reasonable and medically necessary medical or surgical services furnished by a physician while furnishing anesthesia services to the patient. CMS makes payment for these services in accordance with the general physician fee schedule rules in §414.20. These services are described in program operating instructions.

(2) CMS makes no separate payment for other medical or surgical services, such as the pre-anesthetic examination of the patient, pre- or post-operative visits, or usual monitoring functions, that are ordinarily included in the anesthesia service.

(h) *Physician involved in multiple anesthesia services.* If the physician is involved in multiple anesthesia services for the same patient during the same operative session, the carrier makes payment according to the base unit associated with the anesthesia service having the highest base unit value and anesthesia time that encompasses the multiple services. The carrier makes payment for add-on anesthesia codes according to program operating instructions.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 60 FR 63177, Dec. 8, 1995; 64 FR 59441, Nov. 2, 1999; 67 FR 80041, Dec. 31, 2002; 68 FR 63261, Nov. 7, 2003; 74 FR 62006, Nov. 25, 2009]

§ 414.48 Limits on actual charges of nonparticipating suppliers.

(a) *General rule.* A supplier, as defined in § 400.202 of this chapter, who is nonparticipating and does not accept assignment may charge a beneficiary an amount up to the limiting charge described in paragraph (b) of this section.

(b) *Specific limits.* For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the fee schedule amount for nonparticipating suppliers. For items or services CMS excludes from payment under the physician fee schedule (in accordance with section 1848 (j)(3) of the Act), the limiting charge is 115 percent of 95 percent of the payment basis applicable to participating suppliers as calculated in § 414.20(b).

[58 FR 63687, Dec. 2, 1993, as amended at 62 FR 59102, Oct. 31, 1997]

§ 414.50 Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier.

(a) *General rules.* (1) For services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act), if a physician or other supplier bills for the technical component (TC) or professional component (PC) of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control as described in § 413.17 of this chapter) and the diagnostic test is performed by a physician who does not share a practice with the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier. For purposes of this paragraph (a)(1) only, with respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC.

(ii) The billing physician or other supplier's actual charge.

(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

(2) The following requirements are applicable for purposes of paragraph (a)(1) of this section:

(i) The net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.

(ii) A performing physician shares a practice with the billing physician or other supplier if he or she furnishes substantially all (which, for purposes of this section, means ''at least 75 percent'') of his or her professional services through such billing physician or other supplier. The ''substantially all'' requirement will be satisfied if, at the time the billing physician or other supplier submits a claim for a service furnished by the performing physician, the billing physician or other supplier has a reasonable belief that:

(A) For the 12 months prior to and including the month in which the service was performed, the performing physician furnished substantially all of his or her professional services through

the billing physician or other supplier; or

(B) The performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier for the next 12 months (including the month in which the service is performed).

(iii) A physician will be deemed to share a practice with the billing physician or other supplier with respect to the performance of the TC or PC of a diagnostic test if the physician is an owner, employee or independent contractor of the billing physician or other supplier and the TC or PC is performed in the office of the billing physician or other supplier. The ''office of the billing physician or other supplier'' is any medical office space, regardless of number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the same building (as defined in §411.351) in which the ordering physician or other ordering supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined in §411.351 of this chapter), the ''office of the billing physician or other supplier'' is space in which the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. The performance of the TC includes both the conducting of the TC as well as the supervision of the TC.

(b) *Restriction on payment.* (1) The billing physician or other supplier must identify the performing supplier and indicate the performing supplier's net charge for the test. If the billing physician or other supplier fails to provide this information, CMS makes no payment to the billing physician or other supplier and the billing physician or other supplier may not bill the beneficiary.

(2) Physicians and other suppliers that accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(3) Physicians and other suppliers that do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

[72 FR 66400, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 73 FR 69935, Nov. 19, 2008]

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

(a) For assistant-at-surgery services, 65 percent of the amount that would be allowed under the physician fee schedule if the assistant-at-surgery service was furnished by a physician.

(b) For services (other than assistant-at-surgery services) furnished in a hospital, 75 percent of the physician fee schedule amount for the service.

(c) For all other services, 85 percent of the physician fee schedule amount for the service.

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.54 Payment for certified nurse-midwives' services.

(a) For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65 percent of the physician fee schedule amount for the service.

(b) For certified nurse-midwife services furnished on or after January 1, 2011, allowed amounts may not exceed

100 percent of the physician fee schedule amount that would be paid to a physician for the services.

[75 FR 73616, Nov. 29, 2010]

§ 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[63 FR 58911, Nov. 2, 1998]

§ 414.58 Payment of charges for physician services to patients in providers.

(a) *Payment under the physician fee schedule.* In addition to the special conditions for payment in §§ 415.100 through 415.130, and § 415.190 of this chapter, CMS establishes payment for physician services to patients in providers under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *Teaching hospitals.* Services furnished by physicians in teaching hospitals may be made on a reasonable cost basis set forth in § 415.162 of this chapter if the hospital exercises the election described in § 415.160 of this chapter.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 63189, Dec. 8, 1995]

§ 414.60 Payment for the services of CRNAs.

(a) *Basis for payment.* The allowance for the anesthesia service furnished by a CRNA, medically directed or not medically directed, is based on allowable base and time units as defined in § 414.46(a). Beginning with CY 1994—

(1) The allowance for an anesthesia service furnished by a medically directed CRNA is based on a fixed percentage of the allowance recognized for the anesthesia service personally performed by the physician alone, as specified in § 414.46(d)(3); and

(2) The CF for an anesthesia service furnished by a CRNA not directed by a physician may not exceed the CF for a service personally performed by a physician.

(b) *To whom payment may be made.* Payment for an anesthesia service furnished by a CRNA may be made to the CRNA or to any individual or entity (such as a hospital, critical access hospital, physician, group practice, or ambulatory surgical center) with which the CRNA has an employment or contract relationship that provides for payment to be made to the individual or entity.

(c) *Condition for payment.* Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person presenting a claim or request for payment for the service.

[60 FR 63178, Dec. 8, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 59441, Nov. 2, 1999]

§ 414.61 Payment for anesthesia services furnished by a teaching CRNA.

(a) *Basis for payment.* Beginning January 1, 2010, anesthesia services furnished by a teaching CRNA may be paid under one of the following conditions:

(1) The teaching CRNA, who is not under medical direction of a physician, is present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base units payment and is continuously present during anesthesia time in a single case with a student nurse anesthetist.

(2) The teaching CRNA, who is not under the medical direction of a physician, is involved with two concurrent anesthesia cases with student nurse anesthetists. The teaching CRNA must be present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base unit. For the anesthesia time of the two concurrent cases, the teaching CRNA can only be involved with those two concurrent cases and may not perform services for other patients.

(b) *Level of payment.* The allowance for the service of the teaching CRNA, furnished under paragraph (a) of this section, is determined in the same way as for a physician who personally performs the anesthesia service alone as specified in § 414.46(c) of this subpart.

[74 FR 62006, Nov. 25, 2009]

§ 414.62 Fee schedule for clinical psychologist services.

The fee schedule for clinical psychologist services is set at 100 percent of the amount determined for corresponding services under the physician fee schedule.

[62 FR 59102, Oct. 31, 1997]

§ 414.63 Payment for outpatient diabetes self-management training.

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by CMS to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

(c) Limitation on payment. Payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

(2) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(3) Is not receiving services as an outpatient in an RHC or FQHC.

[65 FR 83153, Dec. 29, 2000]

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to non-physician professionals, as specified in paragraph (b) of this section, is the lesser of the actual charges or 80 percent of 85 percent of the physician fee schedule amount.

(b) *To whom payment may be made.* Payment may be made to a registered dietician or nutrition professional qualified to furnish medical nutrition therapy in accordance with part 410, subpart G of this chapter.

(c) *Effective date of payment.* Medicare pays suppliers of medical nutrition therapy on or after the effective date of enrollment of the supplier at the carrier.

(d) *Limitation on payment.* Payment is made only for documented nutritional therapy sessions actually attended by the beneficiary.

(e) *Other conditions for fee-for-service payment.* Payment is made only if the beneficiary:

(1) Is not an inpatient of a hospital, SNF, nursing home, or hospice.

(2) Is not receiving services in an RHC, FQHC or ESRD dialysis facility.

[66 FR 55332, Nov. 1, 2001]

§ 414.65 Payment for telehealth services.

(a) *Professional service.* Medicare payment for the professional service via an interactive telecommunications system is made according to the following limitations:

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth subsequent hospital care service every 3 days), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) and with the limitation of one telehealth nursing facility care service every 30 days), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training (DSMT) services (except for 1 hour of in-person DSMT services to be furnished in the year following the initial DSMT service to ensure effective injection training), and individual and group health and behavior assessment and intervention, and smoking cessation services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Initial inpatient telehealth consultations.* The Medicare payment amount for initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

(2) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(3) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) *Originating site facility fee.* For telehealth services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(c) *Deductible and coinsurance apply.* The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) *Assignment required for physicians, practitioners, and originating sites.* Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) *Sanctions.* A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of

this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2003; 69 FR 66424, Nov. 15, 2004; 70 FR 70332, Nov. 21, 2005; 72 FR 66401, Nov. 27, 2007; 73 FR 69936, Nov. 19, 2008; 74 FR 62006, Nov. 25, 2009; 75 FR 73617, Nov. 29, 2010; 76 FR 73471, Nov. 28, 2011]

§ 414.66 Incentive payments for physician scarcity areas.

(a) *Definition.* As used in this section, the following definitions apply.

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

[69 FR 66424, Nov. 15, 2004]

§ 414.67 Incentive payments for services furnished in Health Professional Shortage Areas.

(a) *Health Professional Shortage Area (HPSA) physician bonus program.* A HPSA physician incentive payment will be made subject to the following:

(1) HPSA bonuses are payable for services furnished by physicians as defined in section 1861(r) of the Act in areas designated as of December 31 of the prior year as geographic primary medical care HPSAs as defined in section 332(a)(1)(A) of the Public Health Service Act.

(2) HPSA bonuses are payable for services furnished by psychiatrists in areas designated as of December 31 of the prior year as geographic mental health HPSAs if the services are not already eligible for the bonus based on being in a geographic primary care HPSA.

(3) Physicians eligible for the HPSA physician bonus are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(4) Physicians furnishing services in areas that are designated as geographic HPSAs prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA bonus payments are made must use the AQ modifier to receive the HPSA physician bonus payment.

(b) *HPSA surgical incentive payment program.* A HPSA surgical incentive payment will be made subject to the following:

(1) A major surgical procedure as defined in §414.2 of this part is furnished by a general surgeon on or after January 1, 2011 and before January 1, 2016 in an area recognized for the HPSA physician bonus program under paragraph (a)(1) of this section.

(2) Payment will be made on a quarterly basis in an amount equal to 10 percent of the Part B payment amount for major surgical procedures furnished as described in paragraph (b)(1) of this section, in addition to the amount the physician would otherwise be paid.

(3) Physicians furnishing services in areas that are designated as geographic HPSAs eligible for the HPSA physician bonus program under paragraph (a)(1) of this section prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA surgical incentive payments are made should report HCPCS modifier -AQ to receive the HPSA surgical incentive payment.

(4) The payment described in paragraph (b)(2) of this section is made to the surgeon or, where the surgeon has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

§ 414.68 Imaging accreditation.

(a) *Scope and purpose.* Section 1834(e) of the Act requires the Secretary to designate and approve independent accreditation organizations for purposes of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services and establish procedures to ensure that the criteria used by an accreditation organization is specific to each imaging modality. Suppliers of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established in section 1848(b) of the Act must become accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

(b) *Definitions.* As used in this section, the following definitions are applicable:

Accredited supplier means a supplier that has been accredited by a CMS-designated accreditation organization as specified in this part.

Advanced diagnostic imaging service means any of the following diagnostic services:

(i) Magnetic resonance imaging.

(ii) Computed tomography.

(iii) Nuclear medicine.

(iv) Positron emission tomography.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified in section 1834(e) of the Act.

(c) *Application and reapplication procedures for accreditation organizations.* An independent accreditation organization applying for approval or reapproval of authority to survey suppliers for purposes of accrediting suppliers furnishing the TC of advanced diagnostic imaging services is required to furnish CMS with all of the following:

(1) A detailed description of how the organization's accreditation criteria satisfy the statutory standards authorized by section 1834(e)(3) of the Act, specifically—

(i) Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services;

(ii) Qualifications and responsibilities of medical directors and supervising physicians (who may be the same person), such as their training in advanced diagnostic imaging services in a residency program, expertise obtained through experience, or continuing medical education courses;

(iii) Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier, including a thorough evaluation of equipment performance and safety;

(iv) Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished;

(v) Procedures to assist the beneficiary in obtaining the beneficiary's imaging records on request; and

(vi) Procedures to notify the accreditation organization of any changes to the modalities subsequent to the organization's accreditation decision.

(2) An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by section 1834(e) of the Act. The accreditation organization must maintain or adopt standards that are equal to, or more stringent than, those of Medicare.

(3) Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.

(4) The organization's proposed fees for accreditation for each modality in which the organization intends to offer

accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(5) Any specific documentation requirements and attestations requested by CMS as a condition of designation under this part.

(6) A detailed description of the organization's survey process, including the following:

(i) Type and frequency of the surveys performed.

(ii) The ability of the organization to conduct timely reviews of accreditation applications, to include the organizations national capacity.

(iii) Description of the organization's audit procedures, including random site visits, site audits, or other strategies for ensuring suppliers maintain compliance for the duration of accreditation.

(iv) Procedures for performing unannounced site surveys.

(v) Copies of the organization's survey forms.

(vi) A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing deficiencies identified with the accreditation requirements, and the procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vii) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(viii) Detailed information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

(A) The number of professional and technical staff that are available for surveys.

(B) The education, employment, and experience requirements surveyors must meet.

(C) The content and length of the orientation program.

(ix) The frequency and types of in-service training provided to survey personnel.

(x) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(xi) The policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

(xii) The policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

(7) Detailed information about the size and composition of survey teams for each category of advanced medical imaging service supplier accredited.

(8) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(9) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and CMS.

(10) The organization's policies and procedures for the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements. These policies and procedures must include notifying CMS of Medicare facilities that fail to meet the requirements of the accrediting organization.

(11) A list of all currently accredited suppliers, the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation.

(12) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(13) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(14) A statement acknowledging that, as a condition for approval of designation, the organization agrees to carry out the following activities:

(i) Prioritize surveys for those suppliers needing to be accredited by January 1, 2012.

(ii) Notify CMS, in writing, of any Medicare supplier that had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.

(iii) Notify all accredited suppliers within 10 calendar days of the organization's removal from the list of designated accreditation organizations.

(iv) Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any significant proposed changes in its accreditation requirements.

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(vi) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accreditation supplier from any source where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.

(vii) Provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditations and trends.

(viii) Attest that the organization will not perform any accreditation surveys of Medicare-participating suppliers with which it has a financial relationship in which it has an interest.

(ix) Conform accreditation requirements to changes in Medicare requirements.

(x) If CMS withdraws an accreditation organization's approved status, work collaboratively with CMS to direct suppliers to the remaining accreditation organizations within a reasonable period of time.

(d) *Determination of whether additional information is needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for designation, the organization must be notified and afforded an opportunity to provide the additional information.

(e) *Visits to the organization's office.* CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, reviewing documents and interviewing the organization's staff.

(f) *Formal notice from CMS.* The accreditation organization will receive a formal notice from CMS stating whether the request for designation has been approved or denied. If approval was denied the notice includes the basis for denial and reconsideration and reapplication procedures.

(g) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(1) Provide CMS with all of the following in written format (either electronic or hard copy):

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers.

(iv) Information about all accredited suppliers against which the accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days after a change in CMS requirements, the accreditation organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(3) The accreditation organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 business days of identifying a deficiency of an accredited supplier that poses immediate jeopardy to a beneficiary or to the general public, the accreditation organization must provide CMS with written notice of the

deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS' notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, the accreditation organization must provide written notice of the withdrawal to all of the organization's accredited suppliers.

(6) The organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(h) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Validation audits.* (i) CMS or its contractor may conduct an audit of an accredited supplier to validate the survey accreditation process of approved accreditation organizations for the TC of advanced diagnostic imaging services.

(ii) The audits must be conducted on a representative sample of suppliers who have been accredited by a particular accrediting organization or in response to allegations of supplier noncompliance with the standards.

(A) When conducted on a representative sample basis, the audit is comprehensive and addresses all of the standards, or may focus on a specific standard in issue.

(B) When conducted in response to an allegation, CMS audits any standards that CMS determines are related to the allegations.

(2) *Notice of intent to withdraw approval.* (i) If, during the audit specified in paragraph (h)(1) of this section, CMS identifies any accreditation programs for which validation audit results indicate—

(A) A 10 percent or greater rate of disparity between findings by the accreditation organization and findings by CMS on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or

(B) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or,

(C) Irrespective of the rate of disparity, widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements; then CMS will give the organization written notice of its intent to withdraw approval as specified in paragraph (h)(3) of this section.

(ii) CMS may also provide the organization written notice of its intent to withdraw approval if an equivalency review, onsite observation, or CMS' daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(3) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers furnishing the technical component of advanced diagnostic imaging service are meeting the established industry standards for each modality and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(i) *Reconsideration.* An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the accreditation organization meet the applicable quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of designation to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(1) *Filing requirements.* (i) The request must be filed within 30 calendar days of

the receipt of CMS notice of an adverse determination or non-renewal.

(ii) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(iii) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(2) *CMS response to a filing request.* In response to a request for reconsideration, CMS provides the accreditation organization with—

(i) The opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(ii) Written notice of the time and place of the informal hearing at least 10 business days before the scheduled date.

(3) *Hearing requirements and rules.* (i) The informal reconsideration hearing is open to all of the following:

(A) CMS.

(B) The organization requesting the reconsideration including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(*3*) Legal counsel.

(ii) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(iii) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(iv) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(v) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(vi) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(vii) The hearing officer's decision is final.

[74 FR 62006, Nov. 25, 2009]

§ 414.80 Incentive payment for primary care services.

(a) *Definitions.* As defined in this section—

Eligible primary care practitioner means one of the following:

(i) A physician (as defined in section 1861(r)(1) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 08-family practice, 11-internal medicine, 37-pediatrics, or 38-geriatrics.

(B) At least 60 percent of the physician's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

(ii) A nurse practitioner, clinical nurse specialist, or physician assistant (as defined in section 1861(aa)(5) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 50-nurse practitioner, 89-certified clinical nurse, or 97-physician assistant.

(B) At least 60 percent of the practitioner's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

Primary care services means—

(i) New and established patient office or other outpatient evaluation and management (E/M) visits;

(ii) Initial, subsequent, discharge, and other nursing facility E/M services;

(iii) New and established patient domiciliary, rest home (for example, boarding home), or custodial care E/M services;

(iv) Domiciliary, rest home (for example, assisted living facility), or home care plan oversight services; and

(v) New and established patient home E/M visits.

(b) *Payment.* (1) For primary care services furnished by an eligible primary care practitioner on or after January 1, 2011 and before January 1, 2016, payment is made on a quarterly basis in an amount equal to 10 percent of the payment amount for the primary care services under Part B, in addition to the amount the primary care practitioner would otherwise be paid for the primary care services under Part B.

(2) The payment described in paragraph (b)(1) of this section is made to the eligible primary care practitioner or, where the physician has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

§ 414.90 Physician Quality Reporting System.

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) 1848(a)—Payment Based on Fee Schedule.

(2) 1848(k)—Quality Reporting System.

(3) 1848(m)—Incentive Payments for Quality Reporting.

(b) *Definitions.* As used in this section, unless otherwise indicated—

Covered professional services means services for which payment is made under, or is based on, the Medicare physician fee schedule as provided under section 1848(k)(3) of the Act and which are furnished by an eligible professional.

Eligible professional means any of the following:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Group practice means a physician group practice, as defined by a TIN, with 25 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN.

Maintenance of Certification Program means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification Program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism. Such a program must include the following:

(i) The program requires the physician to maintain a valid unrestricted license in the United States.

(ii) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

(iii) The program requires a physician to demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

(iv) The program requires successful completion of a qualified maintenance of certification program practice assessment.

Maintenance of Certification Program Practice Assessment means an assessment of a physician's practice that—

(i) Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;

(ii) Includes a survey of patient experience with care; and

(iii) Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under paragraph (h) of this section and then to remeasure to assess performance improvement after such intervention.

Measures group means a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

Physician Quality Reporting System means the physician reporting system under section 1848(k) of the Act for the reporting by eligible professionals of data on quality measures and the incentive payment associated with this physician reporting system.

Performance rate means the percentage of a defined population who receives a particular process of care or achieve a particular outcome for a particular quality measure.

Reporting rate means the percentage of patients that the eligible professional indicated a quality action was or was not performed divided by the total number of patients in the denominator of the measure.

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the Physician Quality Reporting System qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide Physician Quality Reporting System data (as specified by CMS) on behalf of an eligible professional to CMS.

Qualified electronic health record product means an electronic health record vendor's product and version that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate the product's compliance with the Physician Quality Reporting System qualification requirements specified by CMS for a program year. The requirements and process for an electronic health record product to be qualified for the purpose of the Physician Quality Reporting System is separate from the standards, implementation specifications, and certification criteria established for the EHR Incentive Program specified in part 495.

(c) *Incentive payments.* With respect to covered professional services furnished during a reporting period by an eligible professional, if —

(1) There are any quality measures that have been established under the Physician Quality Reporting System that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (g) of this section, such group practice) for such reporting period; and

(2) The eligible professional (or in the case of a group practice under paragraph (g) of this section, the group practice) satisfactorily submits (as determined under paragraph (f) of this section for eligible professionals and paragraph (g) of this section for group practices) to the Secretary data on such quality measures in accordance with the Physician Quality Reporting System for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice) under paragraph (g) of this section, to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (g) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (g) of this section, by the group practice) during the reporting period.

(3) *Applicable quality percent.* The applicable quality percent is as follows:

(i) For 2011, 1.0 percent; and

(ii) For 2012, 2013, and 2014, 0.5 percent;

(4) For purposes of this paragraph—

(i) The eligible professional's (or, in the case of a group practice under paragraph (g) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of an eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments earned by an eligible professional (or in the case of a group practice under paragraph (g) of this section, by a group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(d) *Additional incentive payment.* (1) Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(i) and (ii) of this section, must be increased by 0.5 percentage points.

(2) In order to qualify for the additional incentive payment described in paragraph (d)(1) of this section, an eligible professional must meet the following requirements:

(i) The eligible professional must—

(A) Satisfactorily submit data on quality measures for purposes of this section for a year; and

(B) Have such data submitted on their behalf through a Maintenance of Certification program (as defined in paragraph (b) of this section) that meets:

(*1*) The criteria for a registry (as specified by CMS); or

(*2*) An alternative form and manner determined appropriate by the Secretary.

(ii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program (as defined in paragraph (b) of this section) for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment (as defined in paragraph (b) of this section) for such year.

(iii) A Maintenance of Certification Program submits to the Secretary, on behalf of the eligible professional, information—

(A) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(2)(ii) of this section, which may be in the form of a structural measure);

(B) If requested by the Secretary, on the survey of patient experience with care (as described in paragraph (b) of this section); and

(C) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Use of consensus-based quality measures.* For each program year, CMS will publish the final list of measures and the final detailed measure specifications for all quality measures selected for inclusion in the Physician Quality Reporting System quality measure set for a given program year on a CMS Web site by no later than December 31 of the prior year.

(1) *General rule.* Subject to paragraph (e)(2) of this section, for purposes of reporting data on quality measures for covered professional services furnished during a year, subject to paragraph (f) of this section, the quality measures specified under this paragraph must be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act.

(2) *Exception.* In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance.

(3) *Opportunity to provide input on measures.* For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection

of quality measures applicable to services they furnish.

(f) *Requirements for individual eligible professionals to qualify to receive an incentive payment.* In order to qualify to earn a Physician Quality Reporting System incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (f)(1) of this section and using one of the reporting mechanisms specified in paragraph (f)(2) of this section. Although an eligible professional may attempt to qualify for the Physician Quality Reporting System incentive payment by reporting on both individual Physician Quality Reporting System quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (f)(2) of this section), or reporting for more than one reporting period, he or she will receive only one Physician Quality Reporting System incentive payment per TIN/NPI combination for a program year.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual Physician Quality Reporting System quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of Physician Quality Reporting System measures groups by eligible professionals.

(2) *Reporting mechanisms.* For program year 2011 and subsequent program years, an eligible professional who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS in one of the following manners:

(i) Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(ii) Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified EHR product selected by the eligible professional using a secure data submission method, as required by CMS.

(g) *Requirements for group practices to qualify to receive an incentive payment.* A group practice (as defined in paragraph (b) of this section) will be treated as satisfactorily submitting data on quality measures under Physician Quality

Reporting System for covered professional services for a reporting period, if, in lieu of reporting Physician Quality Reporting System measures, the group practice—

(1) Meets the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option;

(2) Is selected by CMS to participate in the Physician Quality Reporting System group practice reporting option;

(3) Reports measures in the form and manner specified by CMS;

(4) For purposes of paragraph (g), the reporting period is the 12-month period from January 1 through December 31 of such program year;

(5) Meets other requirements for satisfactory reporting specified by CMS; and

(6) Payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Physician Quality Reporting System to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a TIN selected to participate in the Physician Quality Reporting System group practice reporting option for a program year, then for that program year the eligible professional must participate in the Physician Quality Reporting System via the group practice reporting option. For any program year in which the TIN is selected to participate in the Physician Quality Reporting System group practice reporting option, the eligible professional cannot individually qualify for a Physician Quality Reporting System incentive payment by meeting the requirements specified in paragraph (f) of this section.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System under a TIN that is not selected to participate in the Physician Quality Reporting System group practice reporting option for that program year, then the eligible professional may individually qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in paragraph (f) of this section under that TIN.

(h) *Limitations on review.* Except as specified in paragraph (i) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The determination of measures applicable to services furnished by eligible professionals under the Physician Quality Reporting System;

(2) The determination of the payment limitation; and

(3) The determination of any Physician Quality Reporting System incentive payment and the Physician Quality Reporting System payment adjustment.

(i) *Informal review.* Eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) did not satisfactorily submit data on quality measures under the Physician Quality Reporting System.

(1) To request an informal review, an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) must submit a request to CMS within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) CMS will provide a written response within 90 days of the receipt of the original request.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(j) *Public reporting of an eligible professional's or group practice's Physician Quality Reporting System data.* For each

program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) who satisfactorily submitted Physician Quality Reporting System quality measures.

[75 FR 73617, Nov. 29, 2010, as amended at 76 FR 73471, Nov. 28, 2011]

§ 414.92 Electronic Prescribing Incentive Program.

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) Section 1848(a)—Payment Based on Fee Schedule.

(2) Section 1848(m)—Incentive Payments for Quality Reporting.

(b) *Definitions.* As used in this section, unless otherwise indicated—

Certified electronic health record technology means an electronic health record vendor's product and version as described in 45 CFR 170.102.

Covered professional services means services for which payment is made under, or is based on, the Medicare physician fee schedule which are furnished by an eligible professional.

Electronic Prescribing Incentive Program means the incentive payment program established under section 1848(m) of the Act for the adoption and use of electronic prescribing technology by eligible professionals.

Eligible professional means any of the following healthcare professionals who have prescribing authority:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Group practice means a group practice that is—

(i)(A) Defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or

(B) In a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and

(ii) Has indicated its desire to participate in the electronic prescribing group practice option.

Qualified electronic health record product means an electronic health record product and version that, with respect to a particular program year, is designated by CMS as a qualified electronic health record product for the purpose of the Physician Quality Reporting System (as described in § 414.90) and the product's vendor has indicated a desire to have the product qualified for purposes of the product's users to submit information related to the electronic prescribing measure.

Qualified registry means a medical registry or a Maintenance of Certification Program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, is designated by CMS as a qualified registry for the purpose of the Physician Quality Reporting System (as described in § 414.90) and that has indicated its desire to be qualified to submit the electronic prescribing measure on behalf of eligible professionals for the purposes of the Electronic Prescribing Incentive Program.

(c) *Incentive payments and payment adjustments.* (1) *Incentive payments.* Subject to paragraph (c)(3) of this section, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act) or, in the case of a group practice under paragraph (e) of this section, to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable electronic prescribing percent (as specified in paragraph (c)(1)(ii) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed

charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (e) of this section, by the group practice) during the applicable reporting period.

(i) For purposes of paragraph (c)(1) of this section,

(A) The eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(B) In the case of an eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(C) Incentive payments earned by an eligible professional (or in the case of a group practice under paragraph (e) of this section, by a group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(ii) *Applicable electronic prescribing percent.* The applicable electronic prescribing percent is as follows:

(A) For the 2011 and 2012 program years, 1.0 percent.

(B) For the 2013 program year, 0.5 percent.

(iii) *Limitation with respect to electronic health record (EHR) incentive payments.* The provisions of this paragraph do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if, for the electronic health record reporting period the eligible professional (or group practice) receives an incentive payment under section 1848(o)(1)(A) of the Act with respect to a certified electronic health record technology (as defined in section 1848(o)(4) of the Act) that has the capability of electronic prescribing.

(2) *Payment adjustment.* Subject to paragraphs (c)(1)(ii) and (c)(3) of this section, with respect to covered professional services furnished by an eligible professional during 2012, 2013, or 2014, if the eligible professional (or in the case of a group practice under paragraph (e) of this section, the group practice) is not a successful electronic prescriber (as specified by CMS for purposes of the payment adjustment) for an applicable reporting period (as specified by CMS) the fee schedule amount for such services furnished by such professional (or group practice) during the program year (including the fee schedule amount for purposes of determining a payment based on such amount) is equal to the applicable percent (as specified in paragraph (c)(2)(i) of this section) of the fee schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) *Applicable percent.* The applicable percent is as follows:

(A) For 2012, 99 percent;

(B) For 2013, 98.5 percent; and

(C) For 2014, 98 percent.

(ii) *Significant hardship exception.* CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph (c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant hardship exemption from a eRx payment adjustment if one of the following circumstances apply:

(A) From the 2012 payment adjustments by meeting one of the following:

(*1*) The practice is located in a rural area without high speed internet access.

(*2*) The practice is located in an area without sufficient available pharmacies for electronic prescribing.

(*3*) Registration to participate in the Medicare or Medicaid EHR Incentive Program and adoption of Certified EHR Technology.

(*4*) Inability to electronically prescribe due to local, State or Federal law or regulation.

(*5*) Limited prescribing activity.

(*6*) Insufficient opportunities to report the eRx measure due to limitations of the measure's denominator.

(B) From the 2013 and 2014 payment adjustments by meeting one of the following:

(*1*) The eligible professional or group practice is located in a rural area without high speed internet access.

(*2*) The eligible professional or group practice is located in an area without sufficient available pharmacies for electronic prescribing.

(*3*) The eligible professional or group practice is unable to electronically prescribe due to local, State, or Federal law or regulation.

(*4*) The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

(iii) *Other limitations to the payment adjustment*. An eligible professional (or in the case of a group practice under paragraph (b) of this section, a group practice) is exempt from the application of the payment adjustment under paragraph (c)(2) of this section if one of the following applies:

(A) The eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant.

(B) The eligible professional does not have at least 100 cases containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during the 6-month reporting period specified in paragraph (f)(1) of this section.

(3) *Limitation with respect to electronic prescribing quality measures*. The provisions of paragraphs (c)(1) and (c)(2) of this section do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if for the reporting period the allowed charges under section 1848 of the Act for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing measure applies are less than 10 percent of the total of the allowed charges under section 1848 of the Act for all such covered professional services furnished by the eligible professional (or the group practice, as applicable).

(d) *Requirements for individual eligible professionals to qualify to receive an incentive payment*. In order to be considered a successful electronic prescriber and qualify to earn an electronic prescribing incentive payment (subject to paragraph (c)(3) of this section), an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber under section 1848(m)(3)(B) of the Act and as specified by CMS during the reporting period specified in paragraph (d)(1) of this section and using one of the reporting mechanisms specified in paragraph (d)(2) of this section. Although an eligible professional may attempt to qualify for the electronic prescribing incentive payment using more than one reporting mechanism (as specified in paragraph (d)(2) of this section), the eligible professional will receive only one electronic prescribing incentive payment per TIN/NPI combination for a program year.

(1) *Reporting period*. For purposes of this paragraph, the reporting period with respect to a program year is the entire calendar year.

(2) *Reporting mechanisms*. An eligible professional who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to—

(i) CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section;

(ii) A qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section to CMS on the eligible professional's behalf; or

(iii) CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing real or dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(e) *Requirements for group practices to qualify to receive an incentive payment.* (1) A group practice (as defined in paragraph (b) of this section) will be treated as a successful electronic prescriber for covered professional services for a reporting period if the group practice meets the criteria for successful electronic prescriber specified by CMS in the form and manner and at the time specified by CMS.

(2) *No double payments.* Payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Electronic Prescribing Incentive Program to eligible professionals in the group practice for being a successful electronic prescriber.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a TIN selected to participate in the electronic prescribing group practice reporting option for a program year, then for that program year the eligible professional must participate in the Electronic Prescribing Incentive Program via the group practice reporting option. For any program year in which the TIN is selected to participate in the Electronic Prescribing Incentive Program group practice reporting option, the eligible professional cannot individually qualify for an electronic prescribing incentive payment by meeting the requirements specified in paragraph (d) of this section.

(ii) If, for the program year, the eligible professional participates in the Electronic Prescribing Incentive Program under a TIN that is not selected to participate in the Electronic Prescribing Incentive Program group practice reporting option for that program year, then the eligible professional may individually qualify for an electronic prescribing incentive by meeting the requirements specified in paragraph (d) of this section under that TIN.

(f) *Requirements for individual eligible professionals and group practices for the payment adjustment.* In order to be considered a successful electronic prescriber for the electronic prescribing payment adjustment, an individual eligible professional (or, in the case of a group practice under paragraph (b) of this section, a group practice), as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber specified by CMS, in the form and manner specified in paragraph (f)(2) of this section, and during the reporting period specified in paragraph (f)(1) of this section.

(1) *Reporting periods.* (i) For purposes of this paragraph (f), the reporting period for the 2013 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2011 through December 31, 2011.

(B) The 6-month period from January 1, 2012 through June 30, 2012.

(ii) For purposes of this paragraph (f), the reporting period for the 2014 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2012 through December 31, 2012.

(B) The 6-month period from January 1, 2013 through June 30, 2013.

(2) *Reporting mechanisms.* An eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to one of the following:

(i) For the 6- and 12-month reporting periods under paragraph (f)(1) of this section, CMS, by no later than 2 months after the end of the applicable 12-month reporting period or by no later than 1 month after the end of the

applicable 6-month reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section.

(ii) For the 12-month reporting period under paragraph (f)(1) of this section, a qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry submits information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section to CMS on the eligible professional's behalf.

(iii) For the 12-month reporting period under paragraph (f)(1) of this section, CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(g) *Public reporting of an eligible professional's or group practice's Electronic Prescribing Incentive Program data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) who are successful electronic prescribers.

[75 FR 73620, Nov. 29, 2010, as amended at 76 FR 54968, Sept. 6, 2011; 76 FR 73472, Nov. 28, 2011]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§414.102 General payment rules.

(a) *General rule.* For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §414.104.

(b) *Payment classification.* (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in §414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) *Updating the fee schedule amounts.* For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

§414.104 PEN Items and Services.

(a) *Payment rules.* Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

[57 FR 57689, Dec. 7, 1992]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Complex rehabilitative power-driven wheelchair means a power-driven wheelchair that is classified as—

(1) Group 2 power wheelchair with power options that can accommodate rehabilitative features (for example, tilt in space); or

(2) Group 3 power wheelchair.

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

Region means those carrier service areas administered by CMS regional offices.

[57 FR 57689, Dec. 7, 1992, as amended at 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232.

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in §413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in §405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(3) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of beneficiary-owned equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made for replacement parts in a lump sum based on the carrier's consideration of the item. The carrier establishes a reasonable fee for labor associated with repairing, maintaining, and servicing the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for oxygen equipment described in paragraph (e)(2) of this section or for other durable medical equipment as described in §414.229(e).

(2) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period from January 1, 2009 through June 30, 2010.* The carrier makes a maintenance and servicing payment for oxygen equipment other than liquid and gaseous equipment (stationary and portable) as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with §414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for 30 minutes of labor for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(3) *Exception to maintenance and servicing payments.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in §414.222(a);

(ii) Capped rental items, as defined in §414.229(a), that are not beneficiary-owned in accordance with §414.229(d), §414.229(f)(2), or §414.229(h); and

(iii) Capped rental items, as defined in §414.229(a), that are not beneficiary-owned in §414.229(d), §414.229(f)(2), or §414.229(h); and

(iv) Oxygen equipment, as described in §414.226.

(4) *Supplier replacement of beneficiary-owned equipment based on accumulated repair costs.* A supplier that transfers title to a capped rental item to a beneficiary in accordance with §414.229(f)(2) is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment in accordance with §414.210(f)(1). In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.

(5) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period and on or after July 1, 2010.* For oxygen equipment other than liquid and gaseous equipment (stationary and portable), the carrier makes payment as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with §414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) Payment for maintenance and servicing is made based on a reasonable fee not to exceed 10 percent of the purchase price for a stationary oxygen concentrator. This payment includes payment for maintenance and servicing of all oxygen equipment other than liquid or gaseous equipment (stationary or portable).

(iv) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(f) *Payment for replacement of equipment.* If an item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with § 414.226(a).

(3) If the beneficiary elects to obtain a replacement capped rental item, payment is made in accordance with § 414.229(a)(2) or (a)(3).

(4) For all other beneficiary-owned items, if the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

[57 FR 57689, Dec. 7, 1992, as amended at 71 FR 65932, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62009, Nov. 25, 2009]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions.* (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level

of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or

without a backup rate, previously referred to as ''intermittent assist devices with continuous airway pressure devices'').

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995; 71 FR 4525, Jan. 27, 2006]

§ 414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§ 414.226 Oxygen and oxygen equipment.

(a) *Payment rules*—(1) *Oxygen equipment.* Payment for rental of oxygen equipment is made based on a monthly fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 36 months. A period of continuous use is determined under the provisions in § 414.230.

(2) *Oxygen contents.* Payment for purchase of oxygen contents is made based on a monthly fee schedule amount until medical necessity ends.

(b) *Monthly fee schedule amount for items furnished prior to 2007.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(iii) and (iv) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(4) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(i) and (ii) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(5) For 2005 and 2006, the fee schedule amounts determined under paragraph (b)(4) of this section are reduced using the methodology described in section 1834(a)(21)(A) of the Act.

(c) *Monthly fee schedule amount for items furnished for years after 2006.* (1) For 2007, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable equipment only (gaseous or liquid tanks).

(iii) Oxygen generating portable equipment only.

(iv) Stationary oxygen contents only.

(v) Portable oxygen contents only.

(2) The national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by $1.44.

(3) The national limited monthly payment rate for items described in paragraph (c)(1)(ii) of this section is equal to the weighted average of the fee schedule amounts established under paragraph (b)(5) of this section.

(4) The national limited monthly payment rate for items described in paragraph (c)(1)(iii) of this section is equal to the national limited monthly payment rate established under paragraph (c)(5) of this section, multiplied by 24, and divided by 36.

(5) The national limited monthly payment rate for items described in paragraphs (c)(1)(iv) and (c)(1)(v) of this section is equal to 50 percent of the weighted average fee schedule amounts established under paragraph (b)(3) of this section for items described in paragraph (b)(1)(iii) of this section.

(6) Beginning in 2008, CMS makes an annual adjustment to the national limited monthly payment rates for each class of items described in paragraph (c)(1) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts.* (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (e)(2) of this section, the fee schedule amount for items described in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(ii) of this section;

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(e) *Volume adjustments.* (1) The fee schedule amount for an item described in paragraph (c)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (e)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (c)(1)(i) and (c)(1)(ii) or (c)(1)(iii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (e)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

(f) *Furnishing oxygen and oxygen equipment after the 36-month rental cap.* (1) The supplier that furnishes oxygen equipment for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen equipment with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(2) The supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen contents with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(g) *Additional supplier requirements for rentals that begin on or after January 1, 2007.* (1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service

area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain oxygen equipment from a different supplier prior to the expiration of the 36-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the order is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing oxygen equipment, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

[57 FR 57690, Dec. 7, 1992, as amended at 71 FR 65933, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008]

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted

average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 73 FR 69937, Nov. 19, 2008]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in § 414.220 through § 414.228 as follows:

(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(3) For power-driven wheelchairs furnished on or after January 1, 2011, the monthly fee schedule amount for rental equipment equals 15 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 6 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For *1991*. (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in §414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in §414.220(f).

(3) *For years after 1991*. The purchase price is determined using the methodology contained in paragraphs (d) through (f) of §414.220.

(d) *Purchase option*. Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in paragraph (c) of this section.

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing*. (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Rules for capped rental items furnished beginning on or after January 1, 2006*. (1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) *Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007*. (1) The supplier that furnishes an item for

the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) *Purchase of power-driven wheelchairs furnished on or after January 1, 2006.* (1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.

(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.

(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 71 FR 65934, Nov. 9, 2006; 75 FR 73622, Nov. 29, 2010]

§ 414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* (1) A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(2) In the case of a beneficiary receiving oxygen equipment on December 31, 2005, the period of continuous use for the equipment begins on January 1, 2006.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts lnnger than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* (1) If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(2) A new period of continuous use does not begin when a beneficiary changes from one stationary oxygen equipment modality to another or from one portable oxygen equipment modality to another.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

(h) *Oxygen equipment furnished after the 36-month rental period.* A new period of continuous use does not begin under any circumstance in the case of oxygen equipment furnished after the 36-month rental period in accordance with §414.226(f) until the end of the reasonable useful lifetime established for such equipment in accordance with §414.210(f).

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992; 71 FR 65935, Nov. 9, 2006; 73 FR 69937, Nov. 19, 2008]

§414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in §414.220. The payment amount for TENS computed under §414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are

otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) *Applicability.* These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under § 413.170 of this chapter.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of ''supervision of staff'' of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

Routine professional services include all physicians' services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) *Types of routine professional services.* Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses' notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient's medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) *Payment for routine professional services.* Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the ''initial method'' of payment described in § 414.313, (if all of the physicians at the facility elect the initial

method) or under the ''physician MCP method'' described in §414.314. Physician services furnished after July 31, 1983 and before August 6, 1990, are payable only under the MCP method described in §414.314.

§414.313 Initial method of payment.

(a) *Basic rule.* Under this method, the intermediary pays the facility for routine professional services furnished by physicians. Payment is in the form of an add-on to the facility's composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) *Services for which payment is not included in the add-on payment.* (1) Physician administrative services are considered to be facility services and are paid for as part of the facility's composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:

(i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.

(ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.

(iv) Administration of hepatitis B vaccine.

(c) *Physician election of the initial method.* (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) *Termination of the initial method.* (1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—

(i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the termination notice is received by the carrier(s) and intermediary; or

(ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) *Determination of payment amount.* The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) *Publication of payment amount.* Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[55 FR 23441, June 8, 1990, as amended at 62 FR 43674, Aug. 15, 1997]

§414.314 Monthly capitation payment method.

(a) *Basic rules.* (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, either to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of

time, and the capitation amounts are consistent with physicians' charging patterns in their localities.

(4) Payment of the capitation amount for any particular month is contingent upon the physician furnishing to the patient all physician services required by the patient during the month, except those listed in paragraph (b) of this section.

(5) Payment for physician administrative services (§ 414.310) is made to the dialysis facility as part of the facility's composite rate (part 413, subpart H of this subchapter) and not to the physician under the MCP.

(b) *Services not included in the MCP.* (1) Services that are not included in the MCP and which may be paid in accordance with the reasonable charge rules set forth in subpart E of part 405 of this chapter are limited to the following:

(i) Administration of hepatitis B vaccine.

(ii) Covered physician services furnished by another physician when the patient is not available to receive, or the attending physician is not available to furnish, the outpatient services as usual (see paragraph (b)(3) of this section).

(iii) Covered physician services furnished to hospital inpatients, including services related to inpatient dialysis, by a physician who elects not to continue to receive the MCP during the period of inpatient stay.

(iv) Surgical services, including declotting of shunts, other than the insertion of catheters for patients on maintenance peritoneal dialysis who do not have indwelling catheters.

(v) Needed physician services that are—

(A) Furnished by the physician furnishing renal care or by another physician;

(B) Not related to the treatment of the patient's renal condition; and

(C) Not furnished during a dialysis session or an office visit required because of the patient's renal condition.

(2) For the services described in paragraph (b)(1)(v) of this section, the following rules apply:

(i) The physician must provide documentation to show that the services are not related to the treatment of the patient's renal condition and that additional visits are required.

(ii) The carrier's medical staff, acting on the basis of the documentation and appropriate medical consultation obtained by the carrier, determines whether additional payment for the additional services is warranted.

(3) The MCP is reduced in proportion to the number of days the patient is—

(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§ 414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§ 414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§ 414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in

connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in § 405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments.* Payments for covered medical services furnished to the transplant beneficiary by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in § 405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule.* Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at § 413.210.

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* If the conditions in subparagraphs (a)(2)(i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See part 494 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. (§ 410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§ 410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at § 413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at § 413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

(b) *Support services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in § 413.210 of this chapter.

(2) *Exception for home support services furnished prior to January 1, 2011.* If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

(1) *Support services.* The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies.* Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent)

of the national median payment as determined by CMS that would have been made under the prospective payment rates established in § 413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits.* Updated data are incorporated into the payment limits when the prospective payment rates established at § 413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49202, Aug. 12, 2010]

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

[75 FR 49202, Aug. 12, 2010]

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Breach of contract means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements, constitutes a breach of contract.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Corrective action plan (CAP) means a contract supplier's written document with supporting information that describes the actions the contract supplier will take within a specified timeframe to remedy a breach of contract.

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means all rented items within a product category for which payment was made prior to the

implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with § 414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in § 414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in § 414.222 of this part.

(3) Oxygen and oxygen equipment described in § 414.226 of this part.

(4) Other DME described in § 414.229 of this part.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Hearing officer (HO) means an individual, who was not involved with the CBIC recommendation to terminate a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to terminate a DMEPOS Competitive Bidding Program contract.

Hospital has the same meaning as in section 1861(e) of the Act.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

National mail order DMEPOS competitive bidding program means a program whereby contracts are awarded to suppliers for the furnishing of mail order items across the nation.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

Nationwide mail order contract supplier means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

Network means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Non-mail order item means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

Parties to the hearing means the DMEPOS contract supplier and CMS.

Physician has the same meaning as in section 1861(r) of the Act.

Pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Product category means a grouping of related items that are used to treat a similar medical condition.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Small supplier means, a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

§414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in §414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions.* (1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME, and off-the-shelf (OTS) orthotics.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

(2) A physical therapist in private practice (as defined in §410.60(c) of this chapter) or an occupational therapist in private practice (as defined in §410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with §414.408(a).

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

§ 414.406 Implementation of programs.

(a) *Implementation contractor.* CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas.* CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas.* CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items.* CMS designates the items that are included in a competitive bidding program through program instructions or by other means

(e) *Claims processing.* The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006, as amended at 72 FR 18085, Apr. 10, 2007]

§ 414.408 Payment rules.

(a) *Payment basis.* (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under subpart C or subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§ 411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with § 414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items. For contracts entered into beginning on or after January 1, 2011, payment on a lump sum purchase basis is only available for power wheelchairs classified as complex rehabilitative power wheelchairs.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(h) *Rented equipment*—(1) *Capped rental DME.* Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) For contracts entered into beginning on or after January 1, 2011, the monthly fee schedule amount for rental of power wheelchairs equals 15 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 6 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(3) *Additional payment to certain contract suppliers for capped rental DME.* (i) Except as specified in paragraph (h)(3)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(3)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(4) *Maintenance and servicing of rented DME.* Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(5) *Payment for rented enteral nutrition equipment.* Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the

equipment is no longer medically necessary.

(6) *Maintenance and servicing of rented enteral nutrition equipment.* Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(7) *Payment for inexpensive or routinely purchased durable medical equipment.* Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(8) *Payment amounts for rented DME requiring frequent and substantial servicing*—(i) *General rule.* Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception.* The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment*—(1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment*—(1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in § 414.220(a), payment is made in the amount determined under § 414.220(b).

(ii) For other durable medical equipment or capped rental items described

in §414.229, payment is made in the amount determined under §414.229(b).

(iii) For items requiring frequent and substantial servicing described in §414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in §414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in §414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Notification of beneficiaries and CMS by suppliers that choose to become grandfathered suppliers.* (i) *Notification of beneficiaries by suppliers.* (A) *Requirements of notification.* A noncontract supplier that elects to become a grandfathered supplier must provide a 30-day written notification to each Medicare beneficiary that resides in a competitive bidding area and is currently renting a competitively bid item from that supplier. The 30-day notification to the beneficiary must meet the following requirements:

(*1*) Be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program for the CBA in which the beneficiary resides.

(*2*) Identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.

(*3*) Be in writing (for example, by letter or postcard) and the supplier must maintain proof of delivery.

(*4*) State that the supplier is willing to continue to furnish certain rented Durable Medical Equipment (DME), oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (that is, before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.

(*5*) State that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

(*6*) Provide the supplier's telephone number and instruct the beneficiary to call the supplier with any questions and to notify the supplier of his or her decision to use or not use the supplier as a grandfathered supplier.

(*7*) State that the beneficiary can obtain information about the competitive bidding program by calling 1–800–MEDICARE or on the Internet at *http://www.Medicare.gov*.

(B) *Record of beneficiary's choice.* The supplier should obtain an election from the beneficiary regarding whether to use or not use the supplier as a grandfathered supplier. The supplier must maintain a record of its attempts to communicate with the beneficiary to obtain the beneficiary's election regarding grandfathering. When the supplier obtains such an election, the supplier must maintain a record of the beneficiary decision including the date the choice was made, and how the beneficiary communicated his or her choice to the supplier.

(C) *Notification.* If the beneficiary chooses not to continue to receive a grandfathered item(s) from their current supplier, the supplier must provide the beneficiary with 2 more notices in addition to the 30-day notice prior to the supplier picking up its equipment.

(*1*) *10-day notification:* Ten business days prior to picking up the item, the supplier should have direct contact (for example, a phone call) with the beneficiary or the beneficiary's caregiver and receive acknowledgement that the beneficiary understands their equipment will be picked up. This should occur on the first anniversary date after the start of the CBP or on another date agreed to by the beneficiary or the beneficiary's caregiver. The beneficiary's anniversary date occurs every month and is the date of the month on which the item was first delivered to the beneficiary by the current supplier. When a date other than the anniversary date is chosen by the beneficiary or the beneficiary's caregiver, the noncontract supplier will still receive payment up to the anniversary date after the start of the CBP, and the new contract supplier may not bill for any period of time before the anniversary date.

(*2*) *2-day notification:* Two business days prior to picking up the item the supplier should contact the beneficiary or the beneficiary's caregiver by phone to notify the beneficiary of the date the supplier will pick up the item. This date should not be before the beneficiary's first anniversary date that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(D) *Pickup procedures.* (*1*) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(*2*) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(*3*) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are suitable to the beneficiary.

(*4*) The contract supplier may not submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP, and the contract supplier may not begin billing until the first anniversary date that occurs after the beginning of the CBP.

(*5*) The noncontract supplier must submit a claim to be paid up to the first anniversary date that occurs after the beginning of the CBP. Therefore, they should not pick up the equipment before that date unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(ii) *Notification to CMS by suppliers.* A noncontract supplier that elects to become a grandfathered supplier must provide a written notification to CMS of this decision. This notification must meet the following requirements:

(A) State that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment that it is currently furnishing to beneficiaries (that is, before the start of the competitive bidding program) in a CBA and will continue to provide these items to these beneficiaries for the remaining months of the rental period.

(B) Include the following information:

(*1*) Name and address of the supplier.

(*2*) The 6-digit NSC number of the supplier.

(*3*) Product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.

(C) State that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers.

(D) Be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.

(6) *Suppliers that choose not to become grandfathered suppliers.* (i) *Requirement*

for non-grandfathered supplier. A noncontract supplier that elects not to become a grandfathered supplier is required to pick up the item it is currently renting to the beneficiary from the beneficiary's home after proper notification.

(ii) *Notification*. Proper notification includes a 30-day, a 10-day, and a 2-day notice of the supplier's decision not to become a grandfathered supplier to its Medicare beneficiaries who are currently renting certain DME competitively bid item(s) and who reside in a CBA.

(iii) *Requirements of notification*. These notifications must meet all of the requirements listed in paragraph (j)(5)(i) of this section for the 30-day, 10-day and 2-day notices that must be sent by suppliers who decide to be grandfathered suppliers, with the following exceptions for the 30-day notice.

(A) State that, for those items for which the supplier has decided not to be a grandfathered supplier, the supplier will only continue to rent these competitively bid item(s) to its beneficiaries up to the first anniversary date that occurs after the start of the Medicare DMEPOS Competitive Bidding Program.

(B) State that the beneficiary must select a contract supplier for Medicare to continue to pay for these items.

(C) Refer the beneficiary to the contract supplier locator tool on and to 1–800–MEDICARE to obtain information about the availability of contract suppliers for the beneficiary's area.

(iv) *Pickup procedures*. (A) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(B) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(C) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are agreeable to the beneficiary.

(D) The contract supplier cannot submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP.

(7) *Payment for accessories and supplies for grandfathered items*. Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items*. (1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with §414.210(e)(1) of subpart D.

(ii) Payment for parts that are not items (as defined in §414.402) is made in accordance with §414.210(e)(1) of subpart D.

(iii) Payment for parts that are items (as defined in §414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with §414.210(e)(2), (e)(3) and (e)(5) of this part for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for

the replacement item in accordance with paragraph (a)(1) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

(4) For competitions (other than for national mail order items and services) after CY 2011 and prior to CY 2015, the following areas are excluded:

(i) Rural areas.

(ii) MSAs not selected under paragraphs (a)(1) or (a)(2) of this section with a population of less than 250,000.

(iii) An area with low population density within an MSA not selected under paragraphs (a)(1) or (a)(2) of this section.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in § 412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§ 414.411 Special rule in case of competitions for diabetic testing strips conducted on or after January 1, 2011.

(a) *National mail order competitions.* A supplier must demonstrate that their bid submitted as part of a national mail order competition for diabetic testing strips covers the furnishing of a sufficient number of different types of diabetic testing strip products that, in the aggregate, and taking into account volume for the different products, includes at least 50 percent of all the different types of products on the market. A type of diabetic testing strip means

a specific brand and model of testing strips.

(b) *Other competitions.* CMS may apply this special rule to non-mail order or local competitions for diabetic testing strips.

[75 FR 73623, Nov. 29, 2010]

§414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under §414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) *Furnishing of items.* A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) *Separate bids.* For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) Commonly-owned or controlled suppliers. (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

[72 FR 18085, Apr. 10, 2007]

§414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in §424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid

that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* (1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents.* (i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) *Evaluation of bids.* CMS evaluates bids submitted for items within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.

(g) *Special rules for small suppliers*—(1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above

the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under §414.416 of this subpart.

(h) *Sufficient number of suppliers.* (1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under §414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 76 FR 70315, Nov. 10, 2011]

§414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for an item furnished under a competitive bidding program is equal to the median of the bids submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids.

(2) The single payment amount for an item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D.

[72 FR 18085, Apr. 10, 2007]

§414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in §414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member

of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anticompetitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

[72 FR 18085, Apr. 10, 2007]

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

[72 FR 18085, Apr. 10, 2007]

§ 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items

that the contract supplier makes available to other customers.

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—

(i) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) The successor entity submits to CMS the documentation described under §414.414(b) through (d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;

(iii) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(iv) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The successor entity must submit to CMS, within 30 days after the effective date of the change of ownernship and executed novation agreement acceptable to CMS.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(3) Contract suppliers for diabetic testing supplies must furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary. The contract supplier is prohibited from influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions:

(i) Require the contract supplier to submit a corrective action plan;

(ii) Suspend the contract supplier's contract;

(iii) Terminate the contract;

(iv) Preclude the contract supplier from participating in the competitive bidding program;

(v) Revoke the supplier number of the contract supplier; or

(vi) Avail itself of other remedies allowed by law.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2881, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contracts and where CMS has taken action to terminate the supplier's contract. Except as specified in this regulation termination decisions made under this section are final and binding.

(a) *Terminations for breach of contract.* CMS may terminate a supplier's DMEPOS Competitive Bidding Program contract when it determines that the supplier has violated any of the terms of its contract.

(b) *Notice of termination*—(1) *CMS notification.* If CMS determines a supplier to be in breach of its contract either in part or in whole, it will notify the Medicare DMEPOS supplier of the termination by certified mail.

(2) *Content of the notice.* The CMS notice will include the following:

(i) The reasons for the termination.

(ii) The right to request a hearing by a CBIC Hearing Officer, and depending on the nature of the breach, the supplier may also be allowed to submit a CAP in lieu of requesting a hearing by a CBIC Hearing Officer, as specified in paragraph (c)(1)(i) of this section.

(iii) The address to which the written request for a hearing must be mailed.

(iv) The address to which the CAP must be mailed, if applicable.

(v) Penalties that will accompany the termination, such as not being eligible to bid in future rounds of competitive bidding.

(vi) The effective date of termination is 45 days from the date of the notification letter unless a timely hearing request has been filed or a corrective action plan (CAP) has been submitted within 30 days of the date on the notification letter.

(c) *Corrective action plan (CAP)*—(1) *Option for corrective action plan (CAP).* (i) CMS has the option to allow a DMEPOS supplier to provide a written corrective action plan (CAP) to remedy the deficiencies identified in the notice, when CMS determines that the delay in the termination date caused by allowing a CAP will not cause harm to beneficiaries, for example, we would not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime.

(ii) If a supplier chooses not to submit a CAP or if CMS determines that a supplier's CAP is insufficient, the supplier may request a hearing on the termination.

(2) *Submission of a CAP.* (i) A corrective action plan must be submitted within 30 days from the date on the notification letter. If the supplier decides not to submit a corrective action plan the supplier may within 30 days of the date on the termination letter request a hearing by a CBIC hearing officer.

(ii) Suppliers will only have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable or properly implemented, suppliers will receive a subsequent termination notice.

(d) *The purpose of the corrective action plan.* (1) For the supplier to eliminate all of the deficiencies that were identified in the notice to terminate its contract to avoid contract termination.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one-time during the review process based on the deficiencies identified by the CBIC. The

CBIC will submit a recommendation to CMS concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as identified in the notice of termination.

(2) If CMS accepts the CAP, including supplier's designated timeframe for its completion; the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement an acceptable CAP the supplier will receive a subsequent notice that their contract will be terminated within 45 days of the date on that notice.

(f) *Right to request a hearing by the CBIC hearing officer (HO).* (1) A supplier who has received a notice that CMS considers the supplier in breach of contract or that the supplier's CAP is not acceptable has the right to request a hearing before an HO who was not involved with the original determination.

(2) A supplier who wishes to appeal the termination notice must submit a written request to the CBIC. The request for a hearing must be received by the CBIC within 30 days from the date of the notice to terminate.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of the Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, this will result in the termination of the supplier's DMEPOS Competitive Bidding Program contract effective 45 days from the date on the notice to terminate received by the supplier.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the supplier's request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the supplier 30 days before the date of the hearing.

(4) The HO may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days notice of the change.

(5) The HO's scheduling notice must provide the parties to the hearing and the CBIC the following information:

(i) Description of the hearing procedure.

(ii) The general and specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the HO.

(v) All evidence submitted, both from the supplier and CMS, in preparation for the hearing with all affected parties within 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the HO with convincing evidence that it has not breached its contract or that termination is not appropriate.

(2) The supplier's supporting evidence must be submitted with its request for a hearing.

(3) If the Medicare DMEPOS supplier fails to submit this evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the HO within 10 days of receiving a notice announcing the hearing.

(5) The HO will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing and the CBIC within 15 days prior to the scheduled date of the hearing.

(i) *Role of the Hearing Officer.* The HO will conduct a thorough and independent review of the evidence including the information and documentation submitted for the hearing and other information that the HO considers pertinent for the hearing. The role of the HO includes, at a minimum, the following:

(1) Conducts the hearing and decides the order in which the evidence and the arguments of the parties are presented;

(2) Determines the rules on admissibility of the evidence;

(3) Examines the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties.

(5) Determines the rules for requesting documents and other evidence from other parties;

(6) Ensures a complete record of the hearing is made available to all parties to the hearing;

(7) Prepares a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the HO and considered as part of the hearing; and

(8) Complies with all applicable provisions of 42 USC Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing Officer recommendation.* (1) The HO will issue a written recommendation to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the HO has demonstrated that an extension is needed due to the complexity of the matter or heavy workload.

(2) The recommendation will explain the basis and the rationale for the HO's recommendation.

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation.

(k) *CMS' final determination.* (1) CMS' review of the HO recommendation will not allow the supplier to submit new information.

(2) After reviewing the HO recommendation, CMS' decision will be made within 30 days from the date of receipt of the HO's recommendation.

(3) A CMS decision to terminate will indicate the effective date of the termination.

(4) This decision is final and binding.

(l) *Effect of contract termination.* A contract supplier whose contract has been terminated—

(1) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(2) Must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(i) The notice to the beneficiary from the supplier whose contract was terminated must be provided within 15 days of receipt of the final notice of termination.

(ii) The notification to the beneficiaries must inform the beneficiaries that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay these items.

(m) *Effective date of the contract termination.* (1) A supplier's DMEPOS CBP contract is terminated effective on the termination date specified in the notice to the supplier, unless the supplier timely requests a hearing with the HO or the supplier has submitted a CAP under paragraph (c) of this section.

(2) If a supplier requests an HO review of the CMS decision to terminate its contract, and CMS based upon the HO's recommendation terminates the supplier's contract, the effective date of the termination will be the date specified in the post-hearing notice to the supplier indicating CMS's final determination to terminate the contract.

(3) For violations of the terms of the supplier's DMEPOS CBP contract that may harm beneficiaries, such as a supplier providing an inferior product that causes harm to the beneficiary, no

delays of the effective date of the termination will be allowed.

[75 FR 73623, Nov. 29, 2010]

§414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

§414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of supplier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the contract termination, including a detailed explanation of the steps of all attempts to use for other purposes, return or dispose of equipment or other assets purchased or rented for the use in the Round 1 DMEPOS CBP contract performance.

(d) *Items that will not be considered in a claim.* The following items will not be considered in a claim:

(1) The cost of submitting a bid.

(2) Any fees or costs incurred for consulting or marketing.

(3) Costs associated with accreditation or licensure.

(4) Costs incurred before March 20, 2008.

(5) Costs incurred for contract performance after July 14, 2008 except for costs incurred to mitigate damages.

(6) Any profits a supplier may have expected from the contract.

(7) Costs that would have occurred without a contract having been awarded.

(8) Costs for items such as inventory, delivery vehicles, office space and

equipment, personnel, which the supplier did not purchase specifically to perform the contract.

(9) Costs that the supplier has recouped by any means, and may include use of personnel, material, suppliers, or equipment in the supplier's business operations.

(e) *Filing a claim.* (1) A claim, with all supporting documentation, must be filed with the CMS Competitive Bidding Implementation Contractor (CBIC).

(2) Claims must include a statement from a supplier's authorized official certifying the accuracy of the information provided on the claim and all supporting documentation.

(3) The CBIC does not accept electronic submissions of claims for damages.

(f) *Review of claim.* (1) *Role of the CBIC.* (i) The CBIC will review the claim to ensure it is submitted timely, complete, and by an eligible claimant. When the CBIC identifies that a claim is incomplete or not filed timely, it will make a recommendation to the Determining Authority not to process the claim further. Incomplete or untimely claims may be dismissed by the Determining Authority without further processing.

(ii) For complete, timely claims, the CBIC will review the claim on its merits to determine if damages are warranted and may seek further information from the claimant when making its recommendation to the Determining Authority. The CBIC may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iii) The CBIC will make a recommendation to the Determining Authority for each claim filed and include an explanation that supports its recommendation.

(iv) The recommendation must be either to award damages for a particular amount (which may not be the same amount requested by the claimant) or that no damages should be awarded.

(A) If the CBIC recommends that damages are warranted, the CBIC will calculate a recommended reasonable amount of damages based on the claim submitted.

(B) The reasonable amount will consider both costs incurred and the contractor's attempts and action to limit the damages;

(v) The recommendation will be sent to the Determining Authority for a final determination.

(2) *CMS' role as the Determining Authority.* (i) The Determining Authority shall review the recommendation of the CBIC.

(ii) The Determining Authority may seek further information from the claimant or the CBIC in making a concurrence or non-concurrence determination.

(iii) The Determining Authority may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iv) If the Determining Authority concurs with the CBIC recommendation, the Determining Authority shall submit a final signed decision to the CBIC and direct the CBIC to notify the claimant of the decision and the reasons for the final decision.

(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations.* (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination.* The CBIC must mail the

Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

§ 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

Subpart G—Payment for New Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act—procedures for determining the basis for, and amount of, payment for a new clinical diagnostic laboratory test with respect to which a new or substantially revised Healthcare Common Procedure Coding System code is assigned on or after January 1, 2005.

§ 414.502 Definitions.

For purposes of this subpart—

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.504 [Reserved]

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new test, CMS determines the basis for and amount of payment after performance of the following:

(a) CMS makes available to the public (through CMS's Internet Web site) a list that includes codes for which establishment of a payment amount is being considered for the next calendar year.

(b) CMS publishes a FEDERAL REGISTER notice of a meeting to receive public comments and recommendations (and data on which recommendations are based) on the appropriate basis, as specified in § 414.508, for establishing

payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

For a new clinical diagnostic laboratory test that is assigned a new or substantially revised code on or after January 1, 2005, CMS determines the payment amount based on either of the following:

(a) *Crosswalking.* Crosswalking is used if it is determined that a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(1) CMS assigns to the new test code, the local fee schedule amounts and national limitation amount of the existing test.

(2) Payment for the new test code is made at the lesser of the local fee schedule amount or the national limitation amount.

(b) *Gapfilling.* Gapfilling is used when no comparable existing test is available.

(1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:

(i) Charges for the test and routine discounts to charges;

(ii) Resources required to perform the test;

(iii) Payment amounts determined by other payers; and

(iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(2) In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts.

(3) For a new test for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the carrier-specific amounts will pay for the test appropriately. If CMS determines that the carrier-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment.* (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under § 414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (a)(1) of this section.

(ii) If the requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(3) Considering reconsideration requests and other comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment*—(1) *Crosswalking.* (i) For 60 days after making a determination under §414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling.* (i) By April 30 of the year after CMS makes a determination under §414.506(d)(2) or §414.509(a)(3) that the basis for payment for a new test will be gapfilling, CMS posts interim carrier-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim carrier-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim carrier-specific amounts.

(iii) After considering the public comments, CMS will post final carrier-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final carrier-specific amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final payment amounts and the appropriate national limitation amount for the new test.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the national limitation amount for the new test.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date.* If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for reconsideration decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to

reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

[72 FR 66401, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008]

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, ''chemotherapy sensitivity test'' means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response

that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.
(2) Endotracheal intubation.
(3) Central venous line.
(4) Cardiac pacing.
(5) Chest decompression.
(6) Surgical airway.
(7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-Basic). These laws may vary from State to State. For example, only in some States is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line.

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in §410.40(c) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside an urban area, or a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

Urban area means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 71 FR 69787, Dec. 1, 2006]

§ 414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in § 413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in § 414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.

(i) For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in—

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 1 percent higher than otherwise is applicable under this section; and

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(ii) For services furnished during the period July 1, 2008 through December 31, 2011, ambulance services originating in—

(iii) The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is based on loaded miles. Payment for air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* (i) For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and, for services furnished before January 1, 2004, by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles and, for services furnished after December 31, 2003, to every mile over 17 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(ii) For services furnished during the period July 1, 2004 through December 31, 2011, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

(6) *Multiple patients.* The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(7) *Payment rate for mileage greater than 50 miles.* For services furnished during the period July 1, 2004 through December 31, 2008, each loaded ambulance mile greater than 50 (that is, miles 51 and greater) for ambulance transports originating in either urban areas or in rural areas are paid based on a rate that is 25 percent higher than otherwise is applicable under this section.

(d) *Payment.* Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I

of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI–U) (U.S. city average) for the 12-month period ending with June of the previous year and, for 2011 and each subsequent year, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(g) *Adjustments.* The Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule. These rates are not adjusted solely because of changes in the total number of ambulance transports.

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008, through December 31, 2011.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 69 FR 40292, July 1, 2004; 71 FR 69787, Dec. 1, 2006; 73 FR 69937, Nov. 19, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73625, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§ 414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in § 414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment.* For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment.* For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment.* For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment.* For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment.* For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates.* The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in § 414.610(f).

(g) *Exception.* There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§ 414.617 Transition from regional to national ambulance fee schedule.

For services furnished during the period July 1, 2004 through December 31, 2009, the amount for the ground ambulance base rate is subject to a floor amount determined by establishing nine fee schedules based on each of the nine census divisions using the same methodology as used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is less than or equal to the national ground base rate, then it is not used, and the national FS amount applies. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the FS portion of the base rate for that census division is equal to a blend of the national rate and the regional rate in accordance with the following schedule:

Time period	Regional percent	National percent
7/1/04–12/31/04	80	20
CY 2005	60	40
CY 2006	40	60
CY 2007–CY 2009	20	80
CY 2010 and thereafter	0	100

[69 FR 40292, July 1, 2004]

§ 414.620 Publication of the ambulance fee schedule.

(a) Changes in payment rates resulting from incorporation of the annual inflation factor and the productivity adjustment as described in § 414.610(f) will be announced by CMS by instruction and on the CMS Web site.

(b) CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than those described in § 414.610(f).

[75 FR 73626, Nov. 29, 2010]

§ 414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Social Security Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the ''program'') that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal and hepatitis vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs.

§ 414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§ 414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal and influenza vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA	87
LEUPROLIDE ACETATE	81
GOSERELIN ACETATE	80
RITUXIMAB	81
PACLITAXEL	81
DOCETAXEL	80
CARBOPLATIN	81
IRINOTECAN	80
GEMCITABINE HCL	80
PAMIDRONATE DISODIUM	85
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80

Drug	Percentage used to calculate 2004 payment limit
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (See §402 of this chapter).

(c) *Mandatory reporting of anemia quality indicators.* The following provisions are effective January 1, 2008:

(1) Each request for payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level;

(2) Each request for payment for use of erythropoiesis stimulating agents must report the beneficiary's most recent hemoglobin or hematocrit level.

[69 FR 1116, Jan. 7, 2004, as amended at 72 FR 66402, Nov. 27, 2007]

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Drug means both drugs and biologicals.

Manufacturer means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a National Drug Code varies. The method of counting units excludes units of CAP drugs (as defined in § 414.902 of this part) sold to an approved CAP vendor (as defined in § 414.902 of this part) for use under the CAP (as defined in § 414.902 of this part).

[70 FR 69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006; 71 FR 69787, Dec. 1, 2006; 74 FR 62012, Nov. 25, 2009; 76 FR 73473, Nov. 28, 2011]

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.* (1) The manufacturer's average sales price for a quarter for a drug represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

(2) *Price concessions.* (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:

(A) Volume discounts.

(B) Prompt pay discounts.

(C) Cash discounts.

(D) Free goods that are contingent on any purchase requirement.

(E) Chargebacks and rebates (other than rebates under the Medicaid program).

(ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in this paragraph.

(i)(A) For each National Drug Code with at least 12 months of sales (including products for which the manufacturer has redesignated the National Drug Code for the specific product and package size and has 12 months of sales across the prior and current National Drug Codes), after adjusting for exempted sales, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(B) For each National Drug Code with less than 12 months of sales, the calculation described in paragraph (i)(A) of this section is performed for the time period equaling the total number of months of sales.

(ii) The manufacturer multiplies the applicable percentage described in paragraph (a)(3)(i)(A) or (a)(3)(i)(B) of this section by the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted.

(iii) The manufacturer uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter (after adjusting for exempted sales) as the denominator to calculate the manufacturer's average sales price for the National Drug Code for the quarter being submitted.

(iv) *Example.* After adjusting for exempted sales, the total lagged price

concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported, equals $50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33 (average sales price).

(4) *Exempted sales.* (i) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from inclusion in the determination of the best price under section 1927(c)(1)(C)(i) of the Act and sales that are merely nominal in amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act.

(ii) In determining nominal sales exempted under section 1927(c)(1)(C)(ii)(III) of the Act, the manufacturer calculates the average manufacturer price as defined in section 1927(k) of the Act and then identifies sales that are eligible to be considered a nominal sale under section 1927(c)(1)(D) of the Act and are at less than 10 percent of the average manufacturer price. To identify nominal sales, the manufacturer must use the average manufacturer price for the calendar quarter that is the same calendar quarter as the average sales price reporting period.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) The manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label as defined by section 201(k) of the Food, Drug, and Cosmetic Act.

(7) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(b) [Reserved]

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005; 71 FR 69787, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 75 FR 73626, Nov. 29, 2010]

§ 414.806 Penalties associated with the failure to submit timely and accurate ASP data.

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal and Hepatitis B vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

Biosimilar biological product means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Reference biological product means the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product as defined at section 1847A(c)(6)(I) of the Act.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 75 FR 73626, Nov. 29, 2010]

§414.904 Average sales price as the basis for payment.

(a) *Method of payment.* Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(3) For purposes of this paragraph—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

(b) *Multiple source drugs*—(1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity

associated with a billing and payment code, as established by CMS.

(c) *Single source drugs*—(1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when—

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met; and

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(iii) The applicable percentage threshold for average manufacturer price comparisons for CYs 2005 through 2011 is 5 percent. For CY 2012, the applicable percentage threshold for average sales price comparisons is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons for CYs 2005 through 2012 is 5 percent.

(e) *Exceptions to the average sales price*—(1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2006.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable.* In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(5) *Treatment of certain drugs.* Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

(i) If manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits and the unavailability of manufacturer ASP data significantly changes the quarterly payment limit for the billing code when compared to the prior quarter's billing code payment limit, the payment limit is calculated by carrying over the most recent available manufacturer ASP price from a previous quarter for an NDC in the billing code, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported for both the most recently available

previous quarter and the current quarter.

(j) *Biosimilar biological products.* Effective July 1, 2010, the payment amount for a biosimilar biological drug product (as defined in § 414.902 of this subpart) is the sum of the average sales price of all NDCs assigned to the biosimilar biological product as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in § 414.902 of this subpart).

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 70332, Nov. 21, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66402, Nov. 27, 2007; 73 FR 69937, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73626, Nov. 29, 2010; 76 FR 73473, Nov. 28, 2011]

§ 414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under § 414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in § 414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted as a result of the bidding process as described in § 414.910 of this subpart.

(1) *Single payment amount.* (i) A single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the beginning of the payment year.

(ii) The single payment amount is then updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS, and limited by the weighted payment amount established under section 1847A of the Act across all drugs for which a composite bid is required in the category.

(iii) The payment amount for each other drug for which the approved CAP vendor submits a bid in accordance with § 414.910 of this subpart and each other drug that is approved by CMS for the approved CAP vendor to furnish under the CAP is also updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for each HCPCS code and limited by the payment amount established under section 1847A of the Act.

(2) *Updates to payment amount.* (i) The first update is effective on the first day of claims processing for the first quarter of an approved CAP vendor's contract. The first quarterly contract update is based on the reasonable net acquisition cost (RNAC) data reported to CMS or its designee for any purchases of drug before the beginning of CAP

claims processing for the contract period and reported to CMS no later than 30 days before the beginning of CAP claims processing.

(ii) For subsequent quarters, each approved CAP vendor must report to CMS or its designee RNAC data for a quarter of CAP drug purchases within 30 days of the close of that quarter.

(iii) For all quarters, only RNAC data from approved CAP vendors that are supplying CAP drugs under their CAP contract at the time updates are being calculated must be used to calculate updated CAP payment amounts.

(iv) CMS excludes such RNAC data submitted by an approved CAP vendor if, during the time calculations are being done, CMS knows that the approved CAP vendor will not be under contract for the applicable quarterly update.

(v) The payment amount weights must be calculated based on the more recent of the following:

(A) Contract bidding weights.

(B) CAP claims data.

(vi) The payment limit must be determined using the most recent payment limits available to CMS under section 1847A of the Act.

(vii) The following payment amount update calculation must be applied for the group of all drugs for which a composite bid is required.

(A) The most recent previous composite payment amount for the group is updated by—

(*1*) Calculating the percent change in reasonable net acquisition costs for each approved CAP vendor;

(*2*) Calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts; and

(*3*) Limiting the payment as described in paragraph (c)(1) of this section.

(B) The median percent change, subject to the limit described in paragraph (c)(1) of this section, must be the update percentage for that quarter.

(C) The single update percentage must be applied to the payment amount for each drug in the group of drugs for which a composite bid is required in the category.

(viii) The following payment amount update calculation must be applied for each of the following items: Each HCPCS code not included in the composite bid list; Each HCPCS code added to the drug list during the contract period; and each drug that has not yet been assigned a HCPCS code, but for which a HCPCS code will be established.

(A) The most recent previous payment amount for each drug must be updated by calculating the percent change in reasonable net acquisition costs for each approved CAP vendor, then calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts.

(B) The median percent change calculated for each drug, subject to the limit described in paragraph (c)(1) of this section, must be applied to the payment amount for each drug.

(3) *Alternative payment amount.* The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in §414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in §414.902.

(f) *Substitution or addition of drugs on an approved CAP vendor's CAP drug list*—(1) *Short-term substitution of a CAP*

drug. On an occasional basis (for a period of time less than 2 weeks), an approved CAP vendor may agree to furnish a substitute NDC within a HCPCS code on the approved CAP vendor's CAP drug list if the approved CAP vendor—

(i) Is willing to accept the payment amount that was established for the HCPCS code under this section; and

(ii) Obtains the participating CAP physician's prior approval.

(2) *Long-term substitution or addition of a CAP drug*. An approved CAP vendor may submit a request, as specified in paragraph (f)(3) of this section, for approval to substitute an NDC supplied by the approved CAP vendor for another NDC within the same HCPCS code or to add an NDC to the approved CAP vendor's drug list, if at least one of the following criteria is met:

(i) Proposed substitution of an NDC for a period of 2 weeks or longer.

(ii) Proposed addition of one or more NDCs within a HCPCS code included in the CAP drug category specified by CMS or on the approved CAP vendor's approved CAP drug list.

(iii) Proposed addition of—

(A) One or more newly issued HCPCS codes; or

(B) One of the following single indication orphan drug J codes or their updates: J0205, J0256, J9300, J1785, J2355, J3240, J7513, J9010, J9015, J9017, J9160, J9216.

(iv) Beginning January 1, 2007, the proposed addition of a drug(s) that has not yet been assigned a HCPCS code, but for which a HCPCS code must be established.

(v) On or after January 1, 2010, the proposed addition of drugs with similar therapeutic uses to drugs already supplied under the CAP by the approved CAP vendor(s).

(3) *Requesting the addition or substitution of CAP drug*. An approved CAP vendor that meets the one of the criteria specified in paragraph (f)(2) must submit a written request to CMS or its designee. The request must—

(i) Specify the NDC(s) and the respective HCPCS code that is to be added or substituted.

(ii) Address the rationale for the substitution or addition of the NDC(s) or the addition of the HCPCS code(s) as applicable; and

(iii) Address the impact of the substitution of the NDC(s) or the addition of the NDC(s) or HCPCS code(s), or both on—

(A) Patient and drug safety;

(B) Drug waste; and

(C) The potential for cost savings.

(iv) In the case of additions requested under paragraph (f)(2)(v) of this section, address and document the need for such an expansion based on demand for the product(s).

(4) *Approval of a request(s)*. CMS or its designee notifies the approved CAP vendor of its decision.

(i) Except as specified in paragraph (f)(4)(ii) of this section, an approved request is effective at the beginning of the next calendar quarter.

(ii) Approved substitutions for request based on a drug shortage or other exigent circumstance may become effective immediately provided that—

(A) CMS approves the immediate substitution; and

(B) The approved CAP vendor's notifies its CAP participating physicians of the substitution immediately following CMS approval.

(5) *Payment for an approved drug change(s)*. The payment for—

(i) Substituted or added CAP drugs that are within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is the single payment for that HCPCS code, as determined and updated in accordance with paragraph (c)(1) of this section; or

(ii) Added CAP drugs that are not within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is specified under paragraph (c)(2) of this section.

(g) *Deletion of drugs on an approved CAP vendor's CAP drug list*. Deletion of drugs on an approved CAP vendor's CAP drug list due to unavailability requires a written request and approval as described in paragraphs (f)(3)(i) through (iii) and (f)(4) of this section.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 71 FR 9460, Feb. 24, 2006; 74 FR 62012, Nov. 25, 2009]

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor*. (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) The approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(i) have been met (if this subparagraph (a)(2)(iv) applies, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor); or

(v) Other exigent circumstances defined by CMS are present, including—

(A) If, up to and including 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(B) If, more than 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because, based on a change in circumstances of which the participating CAP physician was not previously aware, CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9–CM (if necessary).

(vi) Agrees to accept the particular National Drug Codes (NDCs) supplied by the approved CAP vendor for the duration of the participating CAP physician's enrollment with the approved CAP vendor, subject to paragraphs (a)(3)(vii) and (a)(3)(xiv) of this section. By electing to participate with an approved CAP vendor, the participating CAP physician also agrees to accept the changes to the approved CAP vendor's CAP drug list that have been approved in accordance with § 414.906(f).

(vii) Agrees to place routine orders for CAP drugs at the HCPCs level, except when medical necessity requires a particular formulation on the approved CAP vendor's CAP drug list. Medical necessity must be documented. When the conditions of this paragraph are met, the participating CAP physician may submit a prescription order to the approved CAP vendor that specifies the NDC.

(viii) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(ix) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(x) Agrees to file the Medicare claim within 30 calendar days of the date of drug administration.

(xi) Agrees to submit documentation such as medical records or certification, as necessary, to support payment for a CAP drug;

(xii) Agrees not to transport CAP drugs from one practice location or place of service to another location except in accordance with a written agreement between the participating CAP physician and the approved CAP vendor that requires that drugs are not subjected to conditions that will jeopardize their integrity, stability, and/or sterility while being transported.

(xiii) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xiv) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in §414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under §414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in §414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66402, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§414.912 Conflicts of interest

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at § 414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of paragraph (h) of this section or §414.916(b) of this subpart are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in §414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in §1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor documents, in writing, the following information necessary to verify drug administration:

(i) Beneficiary name.

(ii) Health insurance number.

(iii) Expected date of administration.

(iv) Actual date of administration.

(v) Identity of the participating CAP physician.

(vi) Prescription order number.

(vii) Identity of the individuals who supply and receive the information.

(viii) Dosage supplied.

(ix) Dosage administered.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(i) The approved CAP vendor must comply with the following procedures before it may refuse to make further

shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) An approved CAP vendor that has received payment from the designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the designated carrier and must refund any coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and § 414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (i) of this section delivery means postmark date, or the date the coinsurance bill or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (i)(5)(ii) of this section, if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (i)(6), (i)(7), or (i)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in § 414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and § 414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with § 414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in §414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) Upon notification from CMS of a participating CAP physician's suspension from the program, the approved CAP vendor must cease delivery of CAP drugs to the suspended participating CAP physician until the suspension has been lifted.

(5) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of §414.908(a)(3).

(c) *Reconsideration*—(1) *Right to a reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS or a determination under §414.917(d) denying the participating CAP physician's request to terminate participation in the CAP under §414.908(a)(v) is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing

at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances.

(a) *General rule.* If a participating CAP physician finds an approved CAP

vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with §414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. The approved CAP vendor's contract will remain suspended during the reconsideration process.

(c) *Reconsideration*—(1) *Right to reconsideration.* An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut

CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

(d) *CAP participating physicians' exigent circumstances provision.* The following process must be completed for participating CAP physicians' requests to terminate their participation in the program under exigent circumstances provisions described in § 414.908(a)(2)(v):

(1) The designated carrier must—

(i) Determine whether a request to terminate CAP participation was related to approved CAP vendor service, and if so, forward the issue to the approved CAP vendor's grievance process within 1 business day of the receipt of the request; or

(ii) Continue to investigate, consistent with § 414.916(b)(2) of this chapter, and within 2 business days of receipt, do any of the following:

(A) Request a single, 2-business day extension. No later than the end of any 2-business day extension, the designated carrier must make findings and a recommendation as provided in subparagraph (B) or (C).

(B) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician be permitted to terminate his or her participation in the CAP.

(C) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(ii) In the case of a request made under § 414.908(a)(2)(v)(B), the designated carrier also shall include in its recommendation its finding with respect to whether the request is based on a change in circumstances of which the participating CAP physician was previously unaware.

(2) CMS will consider the carrier's findings and recommendation and may also make its own findings. As a result, CMS will—

(i) Approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation.

(ii) Communicate the decision to the appropriate Medicare contractors and the participating CAP physician.

(3) A denial of the participating CAP physician's request to terminate participation in the CAP must include written notification of the right to request reconsideration under § 414.916(c).

(4) Upon termination of participation in the CAP a physician must—

(i) Continue to submit claims for drugs supplied and administered under the CAP prior to the effective date of the physician's termination from the CAP consistent with § 414.908(a) until all such claims are timely submitted.

(ii) Return any unused CAP drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP to the approved CAP vendor consistent with applicable law and regulation and any agreement with the approved CAP vendor.

(iii) Cooperate in any post-payment review activities on claims submitted under the CAP, as required under section 1847B(a)(3) of the Act.

(5) An approved CAP vendor that has billed and been paid for CAP drugs that have not been administered must refund any payments made by CMS or the beneficiary and his or her supplemental insurer in accordance with § 414.914(h)(3)(i)(2) of this chapter.

[70 FR 39098, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

§ 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

§ 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

(a) *Definitions.* For the purposes of this section:

Compendium means a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium—

(i) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.

(ii) Is indexed by drug or biological.

(iii) Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Publicly transparent process for evaluating therapies means that the process provides that the following information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation:

(i) The internal or external request for listing of a therapy recommendation including criteria used to evaluate the request.

(ii) A listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request.

(iii) A listing of all individuals who have substantively participated in the review or disposition of the request.

(iv) Minutes and voting records of meetings for the review and disposition of the request.

Publicly transparent process for identifying potential conflicts of interests means that process provides that the following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation:

(i) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. This may include, for example, compensation arrangements such as salary, grant, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the review and disposition of the request and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(ii) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(b) *Process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment.* (1) The CMS process—

(i) Receives formal written requests for changes to the list of compendia during a 30 day window beginning January 15 each year.

(ii) Publishes a listing of the timely, complete requests by March 15th and solicits public comment on the requests for 30 days. The listing identifies the requestor and the requested action.

(iii) Considers a compendium's attainment of the MedCAC (Medicare Evidence Development and Coverage Advisory Committee, previously known as the MCAC—Medicare Coverage Advisory Committee) recommended desirable characteristics of compendia (including explicit listing and recommendations) in reviewing requests. CMS may consider additional reasonable factors.

(iv) Considers a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

(v) Considers whether the publication that is the subject of the request meets the definition of a compendium in this section.

(vi) Publishes its decision no later than 90 days after the close of the public comment period.

(2) *Exception.* In addition to the annual process outlined in paragraph (b)(1) of this section, CMS may internally generate a request for changes to the list of compendia at any time.

(c) *Written request for review.* (1) CMS will review a complete, written request that is submitted in writing, electronically or via hard copy (no duplicate submissions) and includes the following:

(i) The full name and contact information of the requestor.

(ii) The full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

(iii) A complete written copy of the compendium that is the subject of the request.

(iv) The specific action that is requested of CMS.

(v) Materials that the requestor must submit for CMS review in support of the requested action.

(vi) A single compendium as its subject.

(d) CMS may at its discretion combine and consider multiple requests that refer to the same compendium.

(e) For the purposes of this section, publication by CMS may be accomplished by posting on the CMS Web site.

[72 FR 66404, Nov. 27, 2007, as amended at 74 FR 62013, Nov. 25, 2009]

Subpart L—Supplying and Dispensing Fees

§ 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§ 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following the first prescription (as specified in paragraph (a)(1) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(3) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *Supplying fees following transplant.* Beginning CY 2006—(1) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following an initial prescription after a transplant (as specified in paragraph (b)(1) of this section) of drugs and biologicals describe in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(c) *30-day dispensing fees.* Beginning CY 2006—(1) A dispensing fee of $57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (c)(1) of this section, a dispensing fee of $33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) *90-day dispensing fee.* Beginning CY 2006, a dispensing fee of $66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005]

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

SOURCE: 72 FR 66404, Nov. 27, 2007, unless otherwise noted.

§ 414.1100 Basis and scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), (d), and (e) of this section payment for CORF services, as defined under § 410.100 of this chapter, is paid the lesser of 80 percent of the following:

(1) The actual charge for the item or service; or

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under § 410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices, and drugs and biologicals.* Supplies and durable medical equipment that are CORF services under § 410.100(l) of this chapter, prosthetic device services that are CORF services under § 410.100(f), orthotic devices that are CORF services under § 410.100(g) of this chapter and drugs and biologicals that are CORF services under § 410.100(k) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d); or

(2) The amount determined under the DMEPOS fee schedule established under part 414 subparts D and F for the item or the single payment amount established under the DMEPOS competitive bidding program provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d).

(d) *Payment for drugs and biologicals.* Drugs and biologicals that are CORF services under § 410.100(j) of this chapter, are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (c); or

(2) The amount determined using the same methodology for drugs (as defined in § 414.704 of this chapter) described in section 1842(o)(1) of the Act provided that payment for such *drug* is not included in the payment amount for other CORF services paid under paragraphs (a) or (c).

(e) *Payment for CORF services when no fee schedule amount for the service.* If there is no fee schedule amount established for a CORF service, payment for the item or service will be the lesser of 80 percent of:

(i) The actual charge for the service provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

(ii) The amount determined under the fee schedule established for a comparable service as specified by the Secretary provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

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415.208 Services of moonlighting residents.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 60 FR 63178, Dec. 8, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 415.1 Basis and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act: Section 1848 establishes a fee schedule for payment for physician services. Section 1861(q) specifies what is included in the term ''physician services'' covered under Medicare. Section 1862(a)(14) sets forth the exclusion of nonphysician services furnished to hospital patients under Part B of Medicare. Section 1886(d)(5)(B) provides for a payment adjustment under the prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983, to account for the indirect costs of medical education. Section 1886(h) establishes the methodology for Medicare payment of the cost of direct GME activities.

(b) *Scope.* This part sets forth rules for fiscal intermediary payments to providers for physician services, Part B carrier payments for physician services to beneficiaries in providers, physician services in teaching settings, and services of residents.

Subpart B—Fiscal Intermediary Payments to Providers for Physician Services

§ 415.50 Scope.

This subpart sets forth rules for payment by fiscal intermediaries to providers for services furnished by physicians. Payment for covered services is made either under the prospective payment system (PPS) to PPS-participating providers in accordance with part 412 of this chapter or under the reasonable cost method to non-PPS participating providers in accordance with part 413 of this chapter.

§ 415.55 General payment rules.

(a) *Allowable costs.* Except as specified otherwise in §§ 413.102 of this chapter (concerning compensation of owners), 415.60 (concerning allocation of physician compensation costs), and 415.162 (concerning payment for physician services furnished to beneficiaries in teaching hospitals), costs a provider incurs for services of physicians are allowable only if the following conditions are met:

(1) The services do not meet the conditions in § 415.102(a) regarding fee schedule payment for services of physicians to a beneficiary in a provider.

(2) The services include a surgeon's supervision of services of a qualified anesthetist, but do not include physician availability services, except for reasonable availability services furnished for emergency rooms and the

services of standby surgical team physicians.

(3) The provider has incurred a cost for salary or other compensation it furnished the physician for the services.

(4) The costs incurred by the provider for the services meet the requirements in § 413.9 of this chapter regarding costs related to patient care.

(5) The costs do not include supervision of interns and residents unless the provider elects reasonable cost payment as specified in § 415.160, or any other costs incurred in connection with an approved GME program that are payable under §§ 413.75 through 413.83 of this chapter.

(b) *Allocation of allowable costs.* The provider must follow the rules in § 415.60 regarding allocation of physician compensation costs to determine its costs of services.

(c) *Limits on allowable costs.* The intermediary must apply the limits on compensation set forth in § 415.70 to determine its payments to a provider for the costs of services.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.60 Allocation of physician compensation costs.

(a) *Definition.* For purposes of this subpart, *physician compensation costs* means monetary payments, fringe benefits, deferred compensation, and any other items of value (excluding office space or billing and collection services) that a provider or other organization furnishes a physician in return for the physician services. Other organizations are entities related to the provider within the meaning of § 413.17 of this chapter or entities that furnish services for the provider under arrangements within the meaning of the Act.

(b) *General rule.* Except as provided in paragraph (d) of this section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

(1) Physician services to the provider (as described in § 415.55);

(2) Physician services to patients (as described in § 415.102); and

(3) Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

(c) *Allowable physician compensation costs.* Only costs allocated to payable physician services to the provider (as described in § 415.55) are allowable costs to the provider under this subpart.

(d) *Allocation of all compensation to services to the provider.* Generally, the total physician compensation received by a physician is allocated among all services furnished by the physician, unless—

(1) The provider certifies that the compensation is attributable solely to the physician services furnished to the provider; and

(2) The physician bills all patients for the physician services he or she furnishes to them and personally receives the payment from or on behalf of the patients. If returned directly or indirectly to the provider or an organization related to the provider within the meaning of § 413.17 of this chapter, these payments are not compensation for physician services furnished to the provider.

(e) *Assumed allocation of all compensation to beneficiary services.* If the provider and physician agree to accept the assumed allocation of all the physician services to direct services to beneficiaries as described under § 415.102(a), CMS does not require a written allocation agreement between the physician and the provider.

(f) *Determination and payment of allowable physician compensation costs.* (1) Except as provided under paragraph (e) of this section, the intermediary pays the provider for these costs only if—

(i) The provider submits to the intermediary a written allocation agreement between the provider and the physician that specifies the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not payable under either Part A or Part B of Medicare; and

(ii) The compensation is reasonable in terms of the time devoted to these services.

(2) In the absence of a written allocation agreement, the intermediary assumes, for purposes of determining reasonable costs of the provider, that 100

percent of the physician compensation cost is allocated to services to beneficiaries as specified in paragraph (b)(2) of this section.

(g) *Recordkeeping requirements.* Except for services furnished in accordance with the assumed allocation under paragraph (e) of this section, each provider that claims payment for services of physicians under this subpart must meet all of the following requirements:

(1) Maintain the time records or other information it used to allocate physician compensation in a form that permits the information to be validated by the intermediary or the carrier.

(2) Report the information on which the physician compensation allocation is based to the intermediary or the carrier on an annual basis and promptly notify the intermediary or carrier of any revisions to the compensation allocation.

(3) Retain each physician compensation allocation, and the information on which it is based, for at least 4 years after the end of each cost reporting period to which the allocation applies.

§ 415.70 Limits on compensation for physician services in providers.

(a) *Principle and scope.* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section, CMS establishes reasonable compensation equivalency limits on the amount of compensation paid to physicians by providers. These limits are applied to a provider's costs incurred in compensating physicians for services to the provider, as described in § 415.55(a).

(2) Limits established under this section do not apply to costs of physician compensation attributable to furnishing inpatient hospital services that are paid for under the prospective payment system implemented under part 412 of this chapter or to costs of physician compensation attributable to approved GME programs that are payable under §§ 413.75 through 413.83 of this chapter.

(3) Compensation that a physician receives for activities that may not be paid for under either Part A or Part B of Medicare is not considered in applying these limits.

(b) *Methodology for establishing limits.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty and type of location using the best available data.

(c) *Application of limits.* If the level of compensation exceeds the limits established under paragraph (b) of this section, Medicare payment is based on the level established by the limits.

(d) *Adjustment of the limits.* The intermediary may adjust limits established under paragraph (b) of this section to account for costs incurred by the physician or the provider related to malpractice insurance, professional memberships, and continuing medical education.

(1) For the costs of membership in professional societies and continuing medical education, the intermediary may adjust the limit by the lesser of—

(i) The actual cost incurred by the provider or the physician for these activities; or

(ii) Five percent of the appropriate limit.

(2) For the cost of malpractice expenses incurred by either the provider or the physician, the intermediary may adjust the reasonable compensation equivalency limit by the cost of the malpractice insurance expense related to the physician service furnished to patients in providers.

(e) *Exception to limits.* An intermediary may grant a provider an exception to the limits established under paragraph (b) of this section only if the provider can demonstrate to the intermediary that it is unable to recruit or maintain an adequate number of physicians at a compensation level within these limits.

(f) *Notification of changes in methodologies and payment limits.* (1) Before the start of a cost reporting period to which limits established under this section will be applied, CMS publishes a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how it calculated the limits.

(2) If CMS proposes to revise the methodology for establishing payment limits under this section, CMS publishes a notice, with opportunity for

public comment, in the FEDERAL REGISTER. The notice explains the proposed basis and methodology for setting limits, specifies the limits that would result, and states the date of implementation of the limits.

(3) If CMS updates limits by applying the most recent economic index data without revising the limit methodology, CMS publishes the revised limits in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

§ 415.100 Scope.

This subpart implements section 1887(a)(1)(A) of the Act by providing general conditions that must be met in order for services furnished by physicians to beneficiaries in providers to be paid for on the basis of the physician fee schedule under part 414 of this chapter. Section 415.102 sets forth the conditions for fee schedule payment for physician services to beneficiaries in providers. Section 415.105 sets forth general requirements for determining the amounts of payment for services that meet the conditions of this section. Sections 415.120 and 415.130 set forth additional conditions for payment for physician services in the specialties of radiology and pathology (laboratory services).

§ 415.102 Conditions for fee schedule payment for physician services to beneficiaries in providers.

(a) *General rule.* If the physician furnishes services to beneficiaries in providers, the carrier pays on a fee schedule basis provided the following requirements are met:

(1) The services are personally furnished for an individual beneficiary by a physician.

(2) The services contribute directly to the diagnosis or treatment of an individual beneficiary.

(3) The services ordinarily require performance by a physician.

(4) In the case of radiology or laboratory services, the additional requirements in § 415.120 or § 415.130, respectively, are met.

(b) *Exception.* If a physician furnishes services in a provider that do not meet the requirements in paragraph (a) of this section, but are related to beneficiary care furnished by the provider, the intermediary pays for those services, if otherwise covered. The intermediary follows the rules in §§ 415.55 and 415.60 for payment on the basis of reasonable cost or PPS, as appropriate.

(c) *Effect of billing charges for physician services to a provider.* (1) If a physician furnishes services that may be paid under the reasonable cost rules in § 415.55 or § 415.60, and paid by the intermediary, or would be paid under those rules except for the PPS rules in part 412 of this chapter, and under the payment rules for GME established by §§ 413.75 through 413.83 of this chapter, neither the provider nor the physician may seek payment from the carrier, beneficiary, or another insurer.

(2) If a physician furnishes services to an individual beneficiary that do not meet the applicable conditions in §§ 415.120 (concerning conditions for payment for radiology services) and 415.130 (concerning conditions for payment for physician pathology services), the carrier does not pay on a fee schedule basis.

(3) If the physician, the provider, or another entity bills the carrier or the beneficiary or another insurer for physician services furnished to the provider, as described in § 415.55(a), CMS considers the provider to which the services are furnished to have violated its provider participation agreement, and may terminate that agreement. See part 489 of this chapter for rules governing provider agreements.

(d) *Effect of physician assumption of operating costs.* If a physician or other entity enters into an agreement (such as a lease or concession) with a provider, and the physician (or entity) assumes some or all of the operating costs of the provider department in which the physician furnishes physician services, the following rules apply:

(1) If the conditions set forth in paragraph (a) of this section are met, the carrier pays for the physician services

under the physician fee schedule in part 414 of this chapter.

(2) To the extent the provider incurs a cost payable on a reasonable cost basis under part 413 of this chapter, the intermediary pays the provider on a reasonable cost basis for the costs associated with producing these services, including overhead, supplies, equipment costs, and services furnished by nonphysician personnel.

(3) The physician (or other entity) is treated as being related to the provider within the meaning of §413.17 of this chapter (concerning cost to related organizations).

(4) The physician (or other entity) must make its books and records available to the provider and the intermediary as necessary to verify the nature and extent of the costs of the services furnished by the physician (or other entity).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.105 Amounts of payment for physician services to beneficiaries in providers.

(a) *General rule.* The carrier determines amounts of payment for physician services to beneficiaries in providers in accordance with the general rules governing the physician fee schedule payment in part 414 of this chapter, except as provided in paragraph (b) of this section.

(b) *Application in certain settings*—(1) *Teaching hospitals.* The carrier applies the rules in subpart D of this part (concerning physician services in teaching settings), in addition to those in this section, in determining whether fee schedule payment should be made for physician services to individual beneficiaries in a teaching hospital.

(2) *Hospital-based ESRD facilities.* The carrier applies §§414.310 through 414.314 of this chapter, which set forth determination of reasonable charges under the ESRD program, to determine the amount of payment for physician services furnished to individual beneficiaries in a hospital-based ESRD facility approved under part 405 subpart U.

§415.110 Conditions for payment: Medically directed anesthesia services.

(a) *General payment rule.* Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in §415.102(a) and the following additional conditions:

(1) For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in §414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) *Medical documentation.* The physician alone inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

[63 FR 58912, Nov. 2, 1998]

§ 415.120 Conditions for payment: Radiology services.

(a) *Services to beneficiaries.* The carrier pays for radiology services furnished by a physician to a beneficiary on a fee schedule basis only if the services meet the conditions for fee schedule payment in § 415.102(a) and are identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of x-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures. The carrier pays for interpretations only if there is a written report prepared for inclusion in the patient's medical record maintained by the hospital.

(b) *Services to providers.* The carrier does not pay on a fee schedule basis for physician services to the provider (for example, administrative or supervisory services) or for provider services needed to produce the x-ray films or other items that are interpreted by the radiologist. However, the intermediary pays the provider for these services in accordance with § 415.55 for provider costs; § 415.102(d)(2) for costs incurred by a physician, such as under a lease or concession agreement; or part 412 of this chapter for payment under PPS.

§ 415.130 Conditions for payment: Physician pathology services.

(a) *Definitions.* The following definitions are used in this section.

(1) *Covered hospital* means, with respect to an inpatient or an outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for this technical component directly to a Medicare carrier.

(2) *Fee-for-service Medicare beneficiaries* means those beneficiaries who are entitled to benefits under Part A or are enrolled under Part B of Title XVIII of the Act or both and are not enrolled in any of the following:

(i) A Medicare+Choice plan under Part C of Title XVIII of the Act.

(ii) A plan offered by an eligible organization under section 1876 of the Act;

(iii) A program of all-inclusive care for the elderly (PACE) under 1894 of the Act; or

(iv) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987.

(b) *Physician pathology services.* The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in § 415.102(a) and are one of the following services:

(1) Surgical pathology services.

(2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.

(3) Clinical consultation services that meet the requirements in paragraph (c) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of paragraphs (c)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

(c) *Clinical consultation services.* For purposes of this section, clinical consultation services must meet the following requirements:

(1) Be requested by the beneficiary's attending physician.

(2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.

(3) Result in a written narrative report included in the beneficiary's medical record.

(4) Require the exercise of medical judgment by the consultant physician.

(d) *Physician pathology services furnished by an independent laboratory.* (1) The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient on or before December 31, 2011, may be paid to the laboratory by the contractor under the physician fee schedule if the Medicare beneficiary is a patient of a covered hospital as defined in paragraph (a)(1) of this section.

(2) For services furnished after December 31, 2011, an independent laboratory may not bill the Medicare contractor for the technical component of physician pathology services furnished to a hospital inpatient or outpatient.

(3) For services furnished on or after January 1, 2008, the date of service policy in §414.510 of this chapter applies to the TC of specimens for physician pathology services.

[60 FR 63178, Dec. 8, 1995, as amended at 64 FR 59442, Nov. 2, 1999; 66 FR 55332, Nov. 1, 2001; 71 FR 69788, Dec. 1, 2006; 72 FR 66405, Nov. 27, 2007; 73 FR 69938, Nov. 19, 2008; 75 FR 73626, Nov. 29, 2010; 76 FR 73473, Nov. 28, 2011]

Subpart D—Physician Services in Teaching Settings

§415.150 Scope.

This subpart sets forth the rules governing payment for the services of physicians in teaching settings and the criteria for determining whether the payments are made as one of the following:

(a) Services to the hospital under the reasonable cost election in §§415.160 through 415.164.

(b) Provider services through the direct GME payment mechanism in §§413.75 through 413.83 of this chapter.

(c) Physician services to beneficiaries under the physician fee schedule as set forth in part 414 of this chapter.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.152 Definitions.

As used in this subpart—

Approved graduate medical education (GME) program means one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education, by the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

(2) A program otherwise recognized as an ''approved medical residency program'' under §413.75(b) of this chapter.

Direct medical and surgical services means services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital making the cost election described in §§415.160 through 415.162.

Nonprovider setting means a setting other than a hospital, skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility in which residents furnish services. These include, but are not limited to, family practice or multispecialty clinics and physician offices.

Resident means one of the following:

(1) An individual who participates in an approved GME program, including programs in osteopathy, dentistry, and podiatry.

(2) A physician who is not in an approved GME program, but who is authorized to practice only in a hospital, for example, individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. For purposes of this subpart, the term *resident* is synonymous with the terms *intern* and *fellow*.

Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.

Teaching physician means a physician (other than another resident) who involves residents in the care of his or her patients.

Teaching setting means any provider, hospital-based provider, or nonprovider settings in which Medicare payment for the services of residents is made under the direct GME payment provisions of §§413.75 through 413.83, or on a reasonable-cost basis under the provisions of §409.26 or §409.40(f) for resident services furnished in skilled nursing facilities or home health agencies, respectively.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 63 FR 26359, May 12, 1998; 70 FR 47490, Aug. 12, 2005; 74 FR 44001, Aug. 27, 2009; 75 FR 50418, Aug. 16, 2010]

§415.160 Election of reasonable cost payment for direct medical and surgical services of physicians in teaching hospitals: General provisions.

(a) *Scope.* A teaching hospital may elect to receive payment on a reasonable cost basis for the direct medical

and surgical services of its physicians in lieu of fee schedule payments that might otherwise be made for these services.

(b) *Conditions.* A teaching hospital may elect to receive these payments only if—

(1) The hospital notifies its intermediary in writing of the election and meets the conditions of either paragraph (b)(2) or paragraph (b)(3) of this section;

(2) All physicians who furnish services to Medicare beneficiaries in the hospital agree not to bill charges for these services; or

(3) All physicians who furnish services to Medicare beneficiaries in the hospital are employees of the hospital and, as a condition of employment, are precluded from billing for these services.

(c) *Effect of election.* If a teaching hospital elects to receive reasonable cost payment for physician direct medical and surgical services furnished to beneficiaries—

(1) Those services and the supervision of interns and residents furnishing care to individual beneficiaries are covered as hospital services, and

(2) The intermediary pays the hospital for those services on a reasonable cost basis under the rules in § 415.162. (Payment for other physician compensation costs related to approved GME programs is made as described in § 413.78 of this chapter.)

(d) *Election declined.* If the teaching hospital does not make this election, payment is made—

(1) For physician services furnished to beneficiaries on a fee schedule basis as described in part 414 subject to the rules in this subpart, and

(2) For the supervision of interns and residents as described in §§ 413.75 through 413.83.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.162 Determining payment for physician services furnished to beneficiaries in teaching hospitals.

(a) *General rule.* Payments for direct medical and surgical services of physicians furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries is made by Medicare on the basis of reasonable cost if the hospital exercises the election as provided for in § 415.160. If this election is made, the following occurs:

(1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries are paid on a reasonable-cost basis, as provided for in paragraph (b) of this section.

(2) Payment for certain medical school costs may be made as provided for in paragraph (c) of this section.

(3) Payments for services donated by volunteer physicians to beneficiaries are made to a fund designated by the organized medical staff of the teaching hospital or medical school as provided for in paragraph (d) of this section.

(b) *Reasonable cost of physician services and supervision of interns and residents.* (1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries in a teaching hospital are payable as provider services on a reasonable-cost basis.

(2) For purposes of this paragraph, *reasonable cost* is defined as the direct salary paid to these physicians, plus applicable fringe benefits.

(3) The costs must be allocated to the services as provided by paragraph (j) of this section and apportioned to program beneficiaries as provided by paragraph (g) of this section.

(4) Other allowable costs incurred by the provider related to the services described in this paragraph are payable subject to the requirements applicable to all other provider services.

(c) *Reasonable costs for the services furnished by a medical school or related organization in a hospital.* An amount is payable to the hospital by CMS under the Medicare program provided that the costs would be payable if incurred directly by the hospital rather than under the arrangement. The amount must not be in excess of the reasonable costs (as defined in paragraphs (c)(1) and (c)(2) of this section) incurred by a teaching hospital for services furnished by a medical school or organization as described in § 413.17 of this chapter for certain costs to the medical school (or a related organization) in furnishing services in the hospital.

(1) *Reasonable costs of physician services*—(i) *When the medical school and the hospital are related organizations.* If the medical school (or organization related to the medical school) and the hospital are related by common ownership or control as described in §413.17 of this chapter—

(A) The costs of these services are allowable costs to the hospital under the provisions of §413.17 of this chapter; and

(B) The reimbursable costs to the hospital are determined under the provisions of this section in the same manner as the costs incurred for physicians on the hospital staff and without regard to payments made to the medical school by the hospital.

(ii) *When the medical school and the hospital are not related organizations.* (A) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school for the costs of those services furnished to all patients, payment is made by Medicare to the hospital for the reasonable cost incurred by the hospital for its payments to the medical school for services furnished to beneficiaries.

(B) Costs incurred under an arrangement must be allocated to the full range of services furnished to the hospital by the medical school physicians on the same basis as provided for under paragraph (j) of this section, and costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided for under paragraph (g) of this section.

(C) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school only for the costs of those services furnished to beneficiaries, costs of the medical school not to exceed 105 percent of the sum of physician direct salaries, applicable fringe benefits, employer's portion of FICA taxes, Federal and State unemployment taxes, and workmen's compensation paid by the medical school or an organization related to the medical school may be recognized as allowable costs of the medical school.

(D) These allowable medical school costs must be allocated to the full range of services furnished by the physicians of the medical school or organization related as provided by paragraph (j) of this section.

(E) Costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided by paragraph (g) of this section.

(2) *Reasonable costs of other than direct medical and surgical services.* These costs are determined in accordance with paragraph (c)(1) of this section except that—

(i) If the hospital makes payment to the medical school for other than direct medical and surgical services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries, these payments are subject to the required cost-finding and apportionment methods applicable to the cost of other hospital services (except for direct medical and surgical services furnished to beneficiaries); or

(ii) If the hospital makes payment to the medical school only for these services furnished to beneficiaries, the cost of these services is not subject to cost-finding and apportionment as otherwise provided by this subpart, and the reasonable cost paid by Medicare must be determined on the basis of the health insurance ratio(s) used in the apportionment of all other provider costs (excluding physician direct medical and surgical services furnished to beneficiaries) applied to the allowable medical school costs incurred by the medical school for the services furnished to all patients of the hospital.

(d) *''Salary equivalent'' payments for direct medical and surgical services furnished by physicians on the voluntary staff of the hospital.* (1) CMS makes payments under the Medicare program to a fund as defined in §415.164 for direct medical and surgical services furnished to beneficiaries on a regularly scheduled basis by physicians on the unpaid voluntary medical staff of the hospital (or medical school under arrangement with the hospital).

(i) These payments represent compensation for contributed medical staff

time which, if not contributed, would have to be obtained through employed staff on a payable basis.

(ii) Payments for volunteer services are determined by applying to the regularly scheduled contributed time an hourly rate not to exceed the equivalent of the average direct salary (exclusive of fringe benefits) paid to all full-time, salaried physicians (other than interns and residents) on the hospital staff or, if the number of full-time salaried physicians is minimal in absolute terms or in relation to the number of physicians on the voluntary staff, to physicians at like institutions in the area.

(iii) This ''salary equivalent'' is a single hourly rate covering all physicians regardless of specialty and is applied to the actual regularly scheduled time contributed by the physicians in furnishing direct medical and surgical services to beneficiaries including supervision of interns and residents in that care.

(iv) A physician who receives any compensation from the hospital or a medical school related to the hospital by common ownership or control (within the meaning of § 413.17 of this chapter) for direct medical and surgical services furnished to any patient in the hospital is not considered an unpaid voluntary physician for purposes of this paragraph.

(v) If, however, a physician receives compensation from the hospital or related medical school or organization only for services that are other than direct medical and surgical services, a salary equivalent payment for the physician's regularly scheduled direct medical and surgical services to beneficiaries in the hospital may be imputed. However, the sum of the imputed value for volunteer services and the physician's actual compensation from the hospital and the related medical school (or organization) may not exceed the amount that would have been imputed if all of the physician's hospital and medical school services (compensated and volunteer) had been volunteer services, or paid at the rate of $30,000 per year, whichever is less.

(2) The following examples illustrate how the allowable imputed value for volunteer services is determined. In each example, it has been assumed that the average salary equivalent hourly rate is equal to the hourly rate for the individual physician's compensated services.

Example No: 1. Dr. Jones received $3,000 a year from Hospital X for services other than direct medical services to all patients, for example, utilization review and administrative services. Dr. Jones also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000 for the cost reporting period. The full imputed value of Dr. Jones' volunteer direct medical services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($3,000) does not exceed $30,000.

Example No: 2. Dr. Smith received $25,000 from Hospital X for services as a department head in a teaching hospital. Dr. Smith also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000. Only $5,000 of the imputed value of volunteer services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($25,000) exceeds the $30,000 maximum amount allowable for all of Dr. Smith's services.

COMPUTATION:

Maximum amount allowable for all services performed by Dr. Smith for purposes of this computation	$30,000
Less compensation received from Hospital X for other than direct medical services to individual patients	$25,000
Allowable amount of imputed value for the volunteer services furnished by Dr. Smith	$5,000

Example No. 3. Dr. Brown is not compensated by Hospital X for any services furnished in the hospital. Dr. Brown voluntarily furnished direct surgical services to beneficiaries for a period of 6 months, and the imputed value of these services amounted to $20,000. The allowable amount of the imputed value for volunteer services furnished by Dr. Brown would be limited to $15,000 ($30,000×6/12).

(3) The amount of the imputed value for volunteer services applicable to beneficiaries and payable to a fund is determined in accordance with the aggregate per diem method described in paragraph (g) of this section.

(4) Medicare payments to a fund must be used by the fund solely for improvement of care of hospital patients or for educational or charitable purposes

(which may include but are not limited to medical and other scientific research).

(i) No personal financial gain, either direct or indirect, from benefits of the fund may inure to any of the hospital staff physicians, medical school faculty, or physicians for whom Medicare imputes costs for purposes of payment into the fund.

(ii) Expenses met from contributions made to the hospital from a fund are not included as a reimbursable cost when expended by the hospital, and depreciation expense is not allowed with respect to equipment or facilities donated to the hospital by a fund or purchased by the hospital from monies in a fund.

(e) *Requirements for payment*—(1) *Physicians on the hospital staff.* The requirements under which the costs of physician direct medical and surgical services (including supervision of interns and residents) to beneficiaries are the same as those applicable to the cost of all other covered provider services except that the costs of these services are separately determined as provided by this section and are not subject to cost-finding as described in §413.24 of this chapter.

(2) *Physicians on the medical school faculty.* Payment is made to a hospital for the costs of services of physicians on the medical school faculty, provided that if the medical school is not related to the hospital (within the meaning of §413.17 of this chapter, concerning cost to related organizations), the hospital does not make payment to the medical school for services furnished to all patients and the following requirements are met: If the hospital makes payment to the medical school for services furnished to all patients, these requirements do not apply. (See paragraph (c)(1)(ii) of this section.)

(i) There is a written agreement between the hospital and the medical school or organization, specifying the types and extent of services to be furnished by the medical school and specifying that the hospital must pay to the medical school an amount at least equal to the reasonable cost (as defined in paragraph (c) of this section) of furnishing the services to beneficiaries.

(ii) The costs are paid to the medical school by the hospital no later than the date on which the cost report covering the period in which the services were furnished is due to CMS.

(iii) Payment for the services furnished under an arrangement would have been made to the hospital had the services been furnished directly by the hospital.

(3) *Physicians on the voluntary staff of the hospital (or medical school under arrangement with the hospital).* If the conditions for payment to a fund outlined in §415.164 are met, payments are made on a ''salary equivalent'' basis (as defined in paragraph (d) of this section) to a fund.

(f) *Requirements for payment for medical school faculty services other than physician direct medical and surgical services.* If the requirements for payment for physician direct medical and surgical services furnished to beneficiaries in a teaching hospital described in paragraph (e) of this section are met, payment is made to a hospital for the costs of medical school faculty services other than physician direct medical and surgical services furnished in a teaching hospital.

(g) *Aggregate per diem methods of apportionment*—(1) *For the costs of physician direct medical and surgical services.* The cost of physician direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined on the basis of an average cost per diem as defined in paragraph (h)(1) of this section for physician direct medical and surgical services to all patients (see §§415.172 through 415.184) for each of the following categories of physicians:

(i) Physicians on the hospital staff.

(ii) Physicians on the medical school faculty.

(2) *For the imputed value of physician volunteer direct medical and surgical services.* The imputed value of physician direct medical and surgical services furnished to beneficiaries in a teaching hospital is determined on the basis of an average per diem, as defined in paragraph (h)(1) of this section, for physician direct medical and surgical services to all patients except that the average per diem is derived from the imputed value of the physician volunteer

direct medical and surgical services furnished to all patients.

(h) *Definitions.* (1) *Average cost per diem for physician direct medical and surgical services (including supervision of interns and residents) furnished in a teaching hospital to patients in each category of physician services described in paragraph (g)(1) of this section* means the amount computed by dividing total reasonable costs of these services in each category by the sum of—

(i) Inpatient days (as defined in paragraph (h)(2) of this section); and

(ii) Outpatient visit days (as defined in paragraph (h)(3) of this section).

(2) *Inpatient days* are determined by counting the day of admission as 3.5 days and each day after a patient's day of admission, except the day of discharge, as 1 day.

(3) *Outpatient visit days* are determined by counting only one visit day for each calendar day that a patient visits an outpatient department or multiple outpatient departments.

(i) *Application.* (1) The following illustrates how apportionment based on the aggregate per diem method for costs of physician direct medical and surgical services furnished in a teaching hospital to patients is determined.

TEACHING HOSPITAL Y

Statistical and financial data:

Total inpatient days as defined in paragraph (h)(2) of this section and outpatient visit days as defined in paragraph (h)(3) of this section	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days where Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the hospital staff as determined in accordance with paragraph (i) of this section	$1,500,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the medical school faculty as determined in accordance with paragraph (i) of this section	$1,650,000

Computation of cost applicable to program for physicians on the hospital staff:

Average cost per diem for direct medical and surgical services to patients by physicians on the hospital staff: $1,500,000 ÷ 75,000 = $20 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $20 per diem × 20,000	$400,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$20,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $20 per diem × 5,000	$100,000

Computation of cost applicable to program for physicians on the medical school faculty:

Average cost per diem for direct medical and surgical services to patients by physicians on the medical school faculty: $1,650,000 ÷ 75,000 = $22 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $22 per diem × 20,000	$440,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$22,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $22 per diem × 5,000	$110,000

(2) The following illustrates how the imputed value of physician volunteer direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined.

Example: The physicians on the medical staff of Teaching Hospital Y donated a total of 5,000 hours in furnishing direct medical and surgical services to patients of the hospital during a cost reporting period and did not receive any compensation from either the hospital or the medical school. Also, the imputed value for any physician volunteer services did not exceed the rate of $30,000 per year per physician.

STATISTICAL AND FINANCIAL DATA:

Total salaries paid to the full-time salaried physicians by the hospital (excluding interns and residents)	$800,000

Total physicians who were paid for an average of 40 hours per week or 2,080 (52 weeks×40 hours per week) hours per year	20
Average hourly rate equivalent: $800,000 ÷ 41,600 (2,080 × 20)	$19.23

Computation of total imputed value of physician volunteer services applicable to all patients:

(Total donated hours × average hourly rate equivalent): 5,000 × $19.23	$96,150
Total inpatient days (as defined in paragraph (h)(2) of this section) and outpatient visit days (as defined in paragraph (h)(3) of this section)	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days if Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000

Computation of imputed value of physician volunteer direct medical and surgical services furnished to Medicare beneficiaries:

Average per diem for physician direct medical and surgical services to all patients: $96,150 ÷ 75,000 = $1.28 per diem

Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $1.28 per diem × 20,000	$25,600
Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $1.28 per diem × 1,000	$1,280
Imputed value of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $1.28 per diem × 5,000	$6,400
Total	$33,280

(j) *Allocation of compensation paid to physicians in a teaching hospital.* (1) In determining reasonable cost under this section, the compensation paid by a teaching hospital, or a medical school or related organization under arrangement with the hospital, to physicians in a teaching hospital must be allocated to the full range of services implicit in the physician compensation arrangements. (However, see paragraph (d) of this section for the computation of the ''salary equivalent'' payments for volunteer services furnished to patients.)

(2) This allocation must be made and must be capable of substantiation on the basis of the proportion of each physician's time spent in furnishing each type of service to the hospital or medical school.

§415.164 Payment to a fund.

(a) *General rules.* Payment for certain voluntary services by physicians in teaching hospitals (as these services are described in §415.160) is made on a salary equivalent basis (as described in §415.162(d)) subject to the conditions and limitations contained in parts 405 and 413 of this chapter and this part 415, to a single fund (as defined in paragraph (b) of this section) designated by the organized medical staff of the hospital (or, if the services are furnished in the hospital by the faculty of a medical school, to a fund as may be designated by the faculty), if the following conditions are met:

(1) The hospital (or medical school furnishing the services under arrangement with the hospital) incurs no actual cost in furnishing the services.

(2) The hospital has an agreement with CMS under part 489 of this chapter.

(3) The intermediary, or CMS as appropriate, has received written assurances that—

(i) The payment is used solely for the improvement of care of hospital patients or for educational or charitable purposes; and

(ii) Neither the individuals who are furnished the services nor any other persons are charged for the services (and if charged, provision is made for the return of any monies incorrectly collected).

(b) *Definition of a fund.* For purposes of paragraph (a) of this section, a *fund* is an organization that meets either of the following requirements:

(1) The organization has and retains exemption, as a governmental entity or under section 501(c)(3) of the Internal Revenue Code (nonprofit educational, charitable, and similar organizations), from Federal taxation.

(2) The organization is an organization of physicians who, under the terms of their employment by an entity that meets the requirements of paragraph (b)(1) of this section, are required to turn over to that entity all

income that the physician organization derives from the physician services.

(c) *Status of a fund.* A fund approved for payment under paragraph (a) of this section has all the rights and responsibilities of a provider under Medicare except that it does not enter into an agreement with CMS under part 489 of this chapter.

§ 415.170 Conditions for payment on a fee schedule basis for physician services in a teaching setting.

Services meeting the conditions for payment in § 415.102(a) furnished in teaching settings are payable under the physician fee schedule if—

(a) The services are personally furnished by a physician who is not a resident; or

(b) The services are furnished by a resident in the presence of a teaching physician except as provided in § 415.172 (concerning physician fee schedule payment for services of teaching physicians), § 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), § 415.176 (concerning renal dialysis services), and § 415.184 (concerning psychiatric services), as applicable.

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. In the case of evaluation and management procedures, the teaching physician must personally document his or her participation in the service in the medical records.

(c) *Payment level.* In the case of services such as evaluation and management for which there are several levels of service codes available for reporting purposes, the appropriate payment level must reflect the extent and complexity of the service when fully furnished by the teaching physician.

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes of lower and mid-level complexity (as specified by CMS in program instructions), carriers may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:

(1) The services must be furnished in a center that is located in an outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining intermediary payments to a hospital under §§ 413.75 through 413.83.

(2) Any resident furnishing the service without the presence of a teaching physician must have completed more than 6 months of an approved residency program.

(3) The teaching physician must not direct the care of more than four residents at any given time and must direct the care from such proximity as to constitute immediate availability. The teaching physician must—

(i) Have no other responsibilities at the time;

(ii) Assume management responsibility for those beneficiaries seen by the residents;

(iii) Ensure that the services furnished are appropriate;

(iv) Review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies; and

(v) Document the extent of the teaching physician's participation in the review and direction of the services furnished to each beneficiary.

(4) The range of services furnished by residents in the center includes all of the following:

(i) Acute care for undifferentiated problems or chronic care for ongoing conditions.

(ii) Coordination of care furnished by other physicians and providers.

(iii) Comprehensive care not limited by organ system, or diagnosis.

(5) The patients seen must be an identifiable group of individuals who consider the center to be the continuing source of their health care and in which services are furnished by residents under the medical direction of teaching physicians.

(b) Nothing in paragraph (a) of this section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical checkups.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 70 FR 47490, Aug. 12, 2005]

§415.176 Renal dialysis services.

In the case of renal dialysis services, physicians who are not paid under the physician monthly capitation payment method (as described in §414.314 of this chapter) must meet the requirements of §§415.170 and 415.172 (concerning physician fee schedule payment for services of teaching physicians).

§415.178 Anesthesia services.

(a) *General rule.* (1) *For services furnished prior to January 1, 2010*, an unreduced physician fee schedule payment may be made if a physician is involved in a single anesthesia procedure involving an anesthesia resident. In the case of anesthesia services, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. The teaching physician cannot receive an unreduced fee if he or she performs services involving other patients during the period the anesthesia resident is furnishing services in a single case. Additional rules for payment of anesthesia services involving residents are specified in §414.46(c)(1)(iii) of this chapter.

(2) *For services furnished on or after January 1, 2010*, payment made under §414.46(e) of this chapter if the teaching anesthesiologist (or different teaching anesthesiologists in the same anesthesia group practice) is present during all critical or key portions of the anesthesia service or procedure involved; and the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(b) *Documentation.* Documentation must indicate the teaching physician's presence during all critical or key portions of the anesthesia procedure and the immediate availability of another teaching anesthesiologist.

[74 FR 62014, Nov. 25, 2009]

§415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(b) *Documentation.* Documentation must indicate that the physician personally performed the interpretation or reviewed the resident's interpretation with the resident.

§ 415.184 Psychiatric services.

To qualify for physician fee schedule payment for psychiatric services furnished under an approved GME program, the physician must meet the requirements of §§ 415.170 and 415.172, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

§ 415.190 Conditions of payment: Assistants at surgery in teaching hospitals.

(a) *Basis, purpose, and scope.* This section describes the conditions under which Medicare pays on a fee schedule basis for the services of an assistant at surgery in a teaching hospital. This section is based on section 1842(b)(7)(D)(I) of the Act and applies only to hospitals with an approved GME residency program. Except as specified in paragraph (c) of this section, fee schedule payment is not available for assistants at surgery in hospitals with—

(1) A training program relating to the medical specialty required for the surgical procedure; and

(2) A resident in a training program relating to the specialty required for the surgery available to serve as an assistant at surgery.

(b) *Definition. Assistant at surgery* means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(c) *Conditions for payment for assistants at surgery.* Payment on a fee schedule basis is made for the services of an assistant at surgery in a teaching hospital only if the services meet one of the following conditions:

(1) Are required as a result of exceptional medical circumstances.

(2) Are complex medical procedures performed by a team of physicians, each performing a discrete, unique function integral to the performance of a complex medical procedure that requires the special skills of more than one physician.

(3) Constitute concurrent medical care relating to a medical condition that requires the presence of, and active care by, a physician of another specialty during surgery.

(4) Are medically required and are furnished by a physician who is primarily engaged in the field of surgery, and the primary surgeon does not use interns and residents in the surgical procedures that the surgeon performs (including preoperative and postoperative care).

(5) Are not related to a surgical procedure for which CMS determines that assistants are used less than 5 percent of the time.

Subpart E—Services of Residents

§ 415.200 Services of residents in approved GME programs.

(a) *General rules.* Services furnished in hospitals by residents in approved GME programs are specifically excluded from being paid as ''physician services'' defined in § 414.2 of this chapter and are payable as hospital services. This exclusion applies whether or not the resident is licensed to practice under the laws of the State in which he or she performs the service. The payment methodology for services of residents in hospitals and hospital-based providers is set forth in §§ 413.75 through 413.83 of this chapter.

(b) *Exception.* For low and mid-level evaluation and management services furnished under certain conditions in centers located in hospital outpatient departments and other ambulatory settings, see § 415.174.

(c) *Definitions.* See § 415.152 for definitions of terms used in this subpart E.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.202 Services of residents not in approved GME programs.

(a) *General rules.* For services of a physician employed by a hospital who is authorized to practice only in a hospital setting and for the services of a resident who is not in any approved GME program, payment is made to the hospital on a Part B reasonable cost

basis regardless of whether the services are furnished to hospital inpatients or outpatients.

(b) *Payment.* For services described in paragraph (a) of this section, payment is made under Part B by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount. No payment is made for other costs of unapproved programs, such as administrative costs related to teaching activities of physicians.

§ 415.204 Services of residents in skilled nursing facilities and home health agencies.

(a) *Medicare Part A payment.* Payment is made under Medicare Part A for interns' and residents' services furnished in the following settings that meet the specified requirements:

(1) *Skilled nursing facility.* Payment to a participating skilled nursing facility may include the cost of services of an intern or resident who is in an approved GME program in a hospital with which the skilled nursing facility has a transfer agreement that provides, in part, for the transfer of patients and the interchange of medical records.

(2) *Home health agency.* A participating home health agency may receive payment for the cost of the services of an intern or resident who is under an approved GME program of a hospital with which the home health agency is affiliated or under common control if these services are furnished as part of the home health visits for a Medicare beneficiary. (Nevertheless, see §§ 413.75 through 413.83 of this chapter for the costs of approved GME programs in hospital-based providers.)

(b) *Medicare Part B payment.* Medical services of a resident of a hospital that are furnished by a skilled nursing facility or home health agency are paid under Medicare Part B if payment is not provided under Medicare Part A. Payment is made under Part B for a resident's services by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.206 Services of residents in nonprovider settings.

Patient care activities of residents in approved GME programs that are furnished in nonprovider settings are payable in one of the following two ways:

(a) *Direct GME payments.* If the conditions in § 413.78 regarding patient care activities and training of residents are met, the time residents spend in nonprovider settings such as clinics, nursing facilities, and physician offices in connection with approved GME programs is included in determining the number of full-time equivalency residents in the calculation of a teaching hospital's resident count. The teaching physician rules on carrier payments in §§ 415.170 through 415.184 apply in these teaching settings.

(b) *Physician fee schedule.* (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that

licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in GME program hospitals.* (1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if all of the following criteria are met:

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in §415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a ''teaching physician'' associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§412.105 of this chapter) and for the direct GME payment (§§413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in §415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center.

(3) Sections 1833(i)(2)(A) and (D) and 1833(a)(1)(G) of the Act specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed in an ASC.

(4) Section 1833(i)(2)(C) of the Act provides that if the Secretary has not updated amounts for ASC facility services furnished during a fiscal year through 2005 or a calendar year beginning with 2006, the amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, except that, in fiscal year 2005, the last quarter of calendar year 2005, and each of the calendar years 2006 through 2009, the increase shall be zero percent.

(5) Section 1833(i)(2)(E) of the Act provides that, with respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system, the payment amount shall be the lesser of the ASC payment rate established under section 1833(i)(2)(A) of the Act or the prospective payment rate for hospital outpatient department services established under section 1833(t)(3)(D) of the Act. The lesser payment amount shall be determined prior to application of any geographic adjustment.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not

requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part.

ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.

Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services.

Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166.

Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006; 72 FR 42544, Aug. 2, 2007; 73 FR 68811, Nov. 18, 2008]

Subpart B—General Conditions and Requirements

§416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in §416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§ 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991; 74 FR 60680, Nov. 20, 2009]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to CMS.* An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS*—(1) *Cause for termination.* CMS may terminate an agreement if it determines that the ASC—

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS.* When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996]

Subpart C—Specific Conditions for Coverage

§ 416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§ 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

(a) *Standard: Contract services.* When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

(b) *Standard: Hospitalization.* (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.

(3) The ASC must—

(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or

(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

(c) *Standard: Disaster preparedness plan.* (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.

(2) The ASC coordinates the plan with State and local authorities, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

[73 FR 68811, Nov. 18, 2008]

§ 416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001; 73 FR 68812, Nov. 18, 2008]

§ 416.43 Conditions for coverage—Quality assessment and performance improvement.

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to—

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that—

(i) Focus on high risk, high volume, and problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI program—

(1) Is defined, implemented, and maintained by the ASC.

(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

[73 FR 68812, Nov. 18, 2008]

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or

otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(*1*) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(*2*) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source;

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) *Standard: Emergency equipment.* The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

(1) Be immediately available for use during emergency situations.

(2) Be appropriate for the facility's patient population.

(3) Be maintained by appropriate personnel.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005; 71 FR 55339, Sept. 22, 2006; 77 FR 29030, May 16, 2012]

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§ 416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

(a) *Standard: Laboratory services.* If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

(b) *Standard: Radiologic services.* (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26 of this chapter.

[73 FR 68812, Nov. 18, 2008]

§ 416.50 Condition for coverage—Patient rights.

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

(a) *Standard: Notice of Rights.* An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(b) *Standard: Disclosure of physician financial interest or ownership.* The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

(c) *Standard: Advance directives.* The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care.

(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(d) *Standard: Submission and investigation of grievances.* The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(2) All allegations must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

(4) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(5) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.

(6) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

(e) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right to the following:

(i) Be free from any act of discrimination or reprisal.

(ii) Voice grievances regarding treatment or care that is (or fails to be) provided.

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

(2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

(f) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(g) *Standard: Confidentiality of clinical records.* The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

[73 FR 68812, Nov. 18, 2008, as amended at 76 FR 65889, Oct. 24, 2011]

§ 416.51 Conditions for coverage—Infection control.

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

(a) *Standard: Sanitary environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) *Standard: Infection control program.* The ASC must maintain an ongoing program designed to prevent, control,

and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is—

(1) Under the direction of a designated and qualified professional who has training in infection control;

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

[73 FR 68813, Nov. 18, 2008]

§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

(a) *Standard: Admission and pre-surgical assessment.* (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.

(3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.

(b) *Standard: Post-surgical assessment.* (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) *Standard: Discharge.* The ASC must—

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

[73 FR 68813, Nov. 18, 2008]

Subpart D—Scope of Benefits for Services Furnished Before January 1, 2008

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Effective for services furnished before January 1, 2008, covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 411.15 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

[47 FR 34094, Aug. 5, 1982, as amended at 71 FR 68226, Nov. 24, 2006]

§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

§ 416.76 Applicability.

The provisions of this subpart apply to facility services furnished before January 1, 2008.

[71 FR 68226, Nov. 24, 2006]

Subpart E—Prospective Payment System for Facility Services Furnished Before January 1, 2008

§ 416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 419 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§ 416.121 Applicability.

The provisions of this subpart apply to facility services furnished before January 1, 2008.

[71 FR 68226, Nov. 24, 2006]

§ 416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

(c) For services furnished on or after January 1, 2007, and before the effective date of implementation of a revised payment system, the ASC payment rate for a surgical procedure is the lesser of the ASC payment rate established under paragraph (a) of this section or the prospective payment rate for the procedure established under § 419.32 of this chapter. The lesser payment amount is determined prior to application of any geographic adjustment.

[56 FR 8844, Mar. 1, 1991, as amended at 71 FR 68226, Nov. 24, 2006]

§ 416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§ 416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

Subpart F—Coverage, Scope of ASC Services, and Prospective Payment System for ASC Services Furnished on or After January 1, 2008

SOURCE: 72 FR 42545, Aug. 2, 2007, unless otherwise noted.

§416.160 Basis and scope.

(a) *Statutory basis.* (1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

(2) Section 1833(a)(1)(G) of the Act provides that, beginning with the implementation date of a revised payment system for ASC facility services furnished in connection with a surgical procedure pursuant to section 1833(i)(1)(A) of the Act, the amount paid shall be 80 percent of the lesser of the actual charge for such services or the amount determined by the Secretary under the revised payment system.

(3) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ASC.

(4) Section 1834(d) of the Act specifies that, when screening colonoscopies or screening flexible sigmoidoscopies are performed in an ASC or hospital outpatient department, payment shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area. Section 1834(d) of the Act also specifies that, in the case of screening flexible sigmoidoscopy and screening colonoscopy services, the payment amounts must not exceed the payment rates established for the related diagnostic services.

(5) Section 1833(a)(1) of the Act requires 100 percent payment for preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the United States Preventive Services Task Force (USPSTF) has given a grade of A or B for any indication or population. Section 1833(b)(1) of the Act also specifies that the Part B deductible shall not

apply with respect to preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) to which the USPSTF has given a grade of A or B for any indication or population.

(b) *Scope.* This subpart sets forth—

(1) The scope of ASC services and the criteria for determining the covered surgical procedures for which Medicare provides payment for the associated facility services and covered ancillary services;

(2) The basis of payment for facility services and for covered ancillary services furnished in an ASC in connection with a covered surgical procedure;

(3) The methodologies by which Medicare determines payment amounts for ASC services.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010]

§ 416.161 Applicability of this subpart.

The provisions of this subpart apply to ASC services furnished on or after January 1, 2008.

§ 416.163 General rules.

(a) Payment is made under this subpart for ASC services specified in §§ 416.164(a) and (b) furnished to Medicare beneficiaries by a participating ASC in connection with covered surgical procedures as determined by the Secretary in accordance with § 416.166.

(b) Payment for physicians' services and payment for anesthetists' services are made in accordance with part 414 of this subchapter.

(c) Payment for items and services other than physicians' and anesthetists' services, as specified in § 416.164(c), is made in accordance with § 410.152 of this subchapter.

§ 416.164 Scope of ASC services.

(a) *Included facility services.* ASC services for which payment is packaged into the ASC payment for a covered surgical procedure under § 416.166 include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facility where the surgical procedures are performed;

(3) Any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver;

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

(5) Medical and surgical supplies not on pass-through status under subpart G of part 419 of this subchapter;

(6) Equipment;

(7) Surgical dressings;

(8) Implanted prosthetic devices, including intraocular lenses (IOLs), and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(9) Implanted DME and related accessories and supplies not on pass-through status under subpart G of part 419 of this subchapter;

(10) Splints and casts and related devices;

(11) Radiology services for which separate payment is not allowed under the OPPS, and other diagnostic tests or interpretive services that are integral to a surgical procedure;

(12) Administrative, recordkeeping and housekeeping items and services;

(13) Materials, including supplies and equipment for the administration and monitoring of anesthesia; and

(14) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Covered ancillary services.* Ancillary items and services that are integral to a covered surgical procedure, as defined in § 416.166, and for which separate payment is allowed include:

(1) Brachytherapy sources;

(2) Certain implantable items that have pass-through status under the OPPS;

(3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue;

(4) Certain drugs and biologicals for which separate payment is allowed under the OPPS;

(5) Certain radiology services for which separate payment is allowed under the OPPS.

(c) *Excluded services.* ASC services do not include items and services outside the scope of ASC services for which payment may be made under part 414 of this subchapter in accordance with § 410.152, including, but not limited to—

(1) Physicians' services (including surgical procedures and all preoperative and postoperative services that are performed by a physician);
(2) Anesthetists' services;
(3) Radiology services (other than those integral to performance of a covered surgical procedure);
(4) Diagnostic procedures (other than those directly related to performance of a covered surgical procedure);
(5) Ambulance services;
(6) Leg, arm, back, and neck braces other than those that serve the function of a cast or splint;
(7) Artificial limbs;
(8) Nonimplantable prosthetic devices and DME.

§416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2008, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the FEDERAL REGISTER and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that—
(1) Generally result in extensive blood loss;
(2) Require major or prolonged invasion of body cavities;
(3) Directly involve major blood vessels;
(4) Are generally emergent or life-threatening in nature;
(5) Commonly require systemic thrombolytic therapy;
(6) Are designated as requiring inpatient care under §419.22(n) of this subchapter;
(7) Can only be reported using a CPT unlisted surgical procedure code; or
(8) Are otherwise excluded under §411.15 of this subchapter.

[72 FR 42545, Aug. 2, 2007, as amended at 76 FR 74582, Nov. 30, 2011]

§416.167 Basis of payment.

(a) *Unit of payment.* Under the ASC payment system, prospectively determined amounts are paid for ASC services furnished to Medicare beneficiaries in connection with covered surgical procedures. Covered surgical procedures and covered ancillary services are identified by codes established under the Healthcare Common Procedure Coding System (HCPCS). The unadjusted national payment rate is determined according to the methodology described in §416.171. The manner in which the Medicare payment amount and the beneficiary coinsurance amount for each ASC service is determined is described in §416.172.

(b) *Ambulatory payment classification (APC) groups and payment weights.* (1) ASC covered surgical procedures are classified using the APC groups described in §419.31 of this subchapter.

(2) For purposes of calculating ASC national payment rates under the methodology described in §416.171, except as specified in paragraph (b)(3) of this section, an ASC relative payment weight is determined based on the APC relative payment weight for each covered surgical procedure and covered ancillary service that has an applicable APC relative payment weight described in §419.31 of this subchapter.

(3) Notwithstanding paragraph (b)(2) of this section, the relative payment weights for services paid in accordance with §416.171(d) are determined so that the national ASC payment rate does not exceed the unadjusted nonfacility practice expense amount paid under the Medicare physician fee schedule for such procedures under subpart B of part 414 of this subchapter.

§416.171 Determination of payment rates for ASC services.

(a) *Standard methodology.* The standard methodology for determining the

national unadjusted payment rate for ASC services is to calculate the product of the applicable conversion factor and the relative payment weight established under § 416.167(b), unless otherwise indicated in this section.

(1) *Conversion factor for CY 2008.* CMS calculates a conversion factor so that payment for ASC services furnished in CY 2008 would result in the same aggregate amount of expenditures as would be made if the provisions in this Subpart F did not apply, as estimated by CMS.

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent.

(ii) For CY 2010 and subsequent calendar years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) *Productivity adjustment.* (A) For calendar year 2011 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) The application of the provisions of paragraph (a)(2)(iii)(A) of this section may result in the update being less than 0.0 for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) *Exception.* The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the FEDERAL REGISTER and/or via the Internet on the CMS Web site. If a payment rate is not available, the following items and services are designated as contractor-priced:

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services as provided in § 416.164(b)(5);

(2) Device-intensive procedures assigned to device-dependent APCs under the OPPS with device costs greater than 50 percent of the APC cost;

(3) Procedures using certain separately paid implantable devices that are approved for transitional pass-through payment in accordance with § 419.66 of this subchapter.

(c) *Transitional payment rates.* (1) ASC payment rates for CY 2008 are a transitional blend of 75 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 25 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(2) ASC payment rates for CY 2009 are a transitional blend of 50 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 50 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(3) ASC payment rates for CY 2010 are a transitional blend of 25 percent of the CY 2007 ASC payment rate for a covered surgical procedure on the CY 2007 ASC list of surgical procedures and 75 percent of the payment rate for the procedure calculated under the methodology described in paragraph (a) of this section.

(4) The national ASC payment rate for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with § 416.166 is the payment rates for the procedure calculated under the methodology described in paragraph (a) of this section.

(5) Covered ancillary services described in § 416.164(b) and surgical procedures identified as covered when performed in an ASC under § 416.166 for the first time beginning on or after January 1, 2008, are not subject to the transitional payment rates applicable in CYs 2008 through 2010 for ASC facility services.

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services.* Notwithstanding the provisions of paragraph

(a) of this section, for any covered surgical procedure under §416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service, excluding those listed in paragraphs (d)(1) and (d)(2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under §414.22(b)(5)(i)(B) of this subchapter multiplied by the conversion factor described in §414.20(a)(3) of this subchapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

(e) *Budget neutrality.* (1) For CY 2008, CMS establishes the conversion factor to result in budget neutrality as estimated by CMS in accordance with paragraph (a)(1) of this section.

(2) For CY 2009 and subsequent calendar years, CMS adjusts the ASC relative payment weights under §416.167(b)(2) as needed so that any updates and adjustments made under §419.50(a) of this subchapter are budget neutral as estimated by CMS.

[72 FR 42545, Aug. 2, 2007, as amended at 75 FR 72264, Nov. 24, 2010; 76 FR 74582, Nov. 30, 2011; 77 FR 277, Jan. 4, 2012]

§416.172 Adjustments to national payment rates.

(a) *General rule.* Contractors adjust the payment rates established for ASC services to determine Medicare program payment and beneficiary coinsurance amounts in accordance with paragraphs (b) through (g) of this section.

(b) *Lesser of actual charge or geographically adjusted payment rate.* Payments to ASCs equal 80 percent of the lesser of—

(1) The actual charge for the service; or

(2) The geographically adjusted payment rate determined under this subpart.

(c) *Geographic adjustment*—(1) *General rule.* Except as provided in paragraph (c)(2) of this section, the national ASC payment rates established under §416.171 for covered surgical procedures are adjusted for variations in ASC labor costs across geographic areas using wage index values, labor and nonlabor percentages, and localities specified by the Secretary.

(2) *Exception.* The geographic adjustment is not applied to the payment rates set for drugs, biologicals, devices with OPPS transitional pass-through payment status, and brachytherapy sources.

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§410.152(a) and (i)(2) of this subchapter.

(e) *Payment reductions for multiple surgical procedures*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, when more than one covered surgical procedure for which payment is made under the ASC payment system is performed during an operative session, the Medicare program payment amount and the beneficiary coinsurance amount are based on—

(i) 100 percent of the applicable ASC payment amount for the procedure with the highest national unadjusted ASC payment rate; and

(ii) 50 percent of the applicable ASC payment amount for all other covered surgical procedures.

(2) *Exception: Procedures not subject to multiple procedure discounting.* CMS may apply any policies or procedures used with respect to multiple procedures under the prospective payment system for hospital outpatient department services under Part 419 of this subchapter as may be consistent with the equitable and efficient administration of this part.

(f) *Interrupted procedures.* When a covered surgical procedure or covered ancillary service is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment

amount and the beneficiary coinsurance amount are based on one of the following—

(1) The full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(2) One-half of the full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before the anesthesia is induced; or

(3) One-half of the full program and beneficiary coinsurance amounts if a covered surgical procedure or covered ancillary service for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the service is to be provided.

(g) *Payment adjustment for new technology intraocular lenses (NTIOLs).* A payment adjustment will be made for insertion of an IOL approved as belonging to a class of NTIOLs as defined in subpart G.

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the FEDERAL REGISTER and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

[76 FR 74582, Nov. 30, 2011]

§ 416.178 Limitations on administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The classification system;

(b) Relative weights;

(c) Payment amounts; and

(d) Geographic adjustment factors.

§ 416.179 Payment and coinsurance reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for a covered surgical procedure for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device not on pass-through status under subpart G of part 419 of this subchapter when one of the following situations occur:

(1) The device is replaced without cost to the ASC or the beneficiary;

(2) The ASC receives full credit for the cost of a replaced device; or

(3) The ASC receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the ASC payment for the covered surgical procedure.* (1) The amount of the reduction to the ASC payment made under paragraphs (a)(1) and (a)(2) of this section is calculated in the same manner as the device payment reduction that would be applied to the ASC payment for the covered surgical procedure in order to remove predecessor device costs so that the ASC payment amount for a device with pass-through status under § 419.66 of this subchapter represents the full cost of the device, and no packaged device payment is provided through the ASC payment for the covered surgical procedure.

(2) The amount of the reduction to the ASC payment made under paragraph (a)(3) of this section is 50 percent of the payment reduction that would be calculated under paragraph (b)(1) of this section.

(c) *Amount of beneficiary coinsurance.* The beneficiary coinsurance is calculated based on the ASC payment for the covered surgical procedure after application of the reduction under paragraph (b) of this section.

[72 FR 42545, Aug. 2, 2007, as amended at 72 FR 66932, No. 27, 2007]

Subpart G—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Service Centers

SOURCE: 71 FR 68226, Nov. 24, 2006, unless otherwise noted.

§416.180 Basis and scope.

(a) *Basis.* This subpart implements section 141 of Public Law 103–432, which provides for adjustments to payment amounts for new technology intraocular lenses (IOLs) furnished at ambulatory surgical centers (ASCs).

(b) *Scope.* This subpart sets forth—

(1) The process for interested parties to request that CMS review the appropriateness of the ASC facility fee for insertion of an IOL. This process includes a review of whether that payment is reasonable and related to the cost of acquiring a lens determined by CMS as belonging to a class of new technology IOLs;

(2) Factors that CMS considers for determination of a new class of new technology IOLs; and

(3) Application of the payment adjustment.

§416.185 Process for establishing a new class of new technology IOLs.

(a) *Announcement of deadline for requests for review.* CMS announces the deadline for each year's requests for review of a new class of new technology IOLs in the final rule updating the ASC payment rates for that calendar year.

(b) *Announcement of new classes of new technology IOLs for which review requests have been made and solicitation of public comments.* CMS announces the requests for review received in a calendar year and the deadline for public comments regarding the requests in the proposed rule updating the ASC payment rates for the following calendar year. The deadline for submission of public comments is 30 days following the date of the publication of the proposed rule.

(c) *Announcement of determinations regarding requests for review.* CMS announces its determinations for a calendar year in the final rule updating the ASC payment rates for the following calendar year. CMS publishes the codes and effective dates allowed for those lenses recognized by CMS as belonging to a class of new technology IOLs. New classes of new technology IOLs are effective 30 days following the date of publication of the final rule.

§416.190 Request for review of payment amount.

(a) *When requests can be submitted.* A request for review of the appropriateness of ASC payment for insertion of an IOL that might qualify for a payment adjustment as belonging to a new class of new technology IOLs must be submitted to CMS in accordance with the annual published deadline.

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the criteria of a new technology IOL under §416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), the requestor must clearly identify all information that is to be characterized as confidential.

§416.195 Determination of membership in new classes of new technology IOLs.

(a) *Factors to be considered.* CMS uses the following criteria to determine whether an IOL qualifies for a payment adjustment as a member of a new class of new technology IOLs when inserted at an ASC:

(1) The IOL is approved by the FDA.

(2) Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison

to currently available IOLs are approved by the FDA for use in labeling and advertising.

(3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.

(4) Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Superior outcomes include:

(i) Reduced risk of intraoperative or postoperative complication or trauma;

(ii) Accelerated postoperative recovery;

(iii) Reduced induced astigmatism;

(iv) Improved postoperative visual acuity;

(v) More stable postoperative vision;

(vi) Other comparable clinical advantages.

(b) *CMS determination of eligibility for payment adjustment.* CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and makes a determination as follows:

(1) The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.

(2) The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.

(3) The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

§ 416.200 Payment adjustment.

(a) CMS establishes the amount of the payment adjustment for classes of new technology IOLs through proposed and final rulemaking in connection with ASC facility services.

(b) CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for the 5-year period of time established for that class.

(c) Upon expiration of the 5-year period of the payment adjustment, payment reverts to the standard rate for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to a class of new technology IOLs must submit claims using billing codes specified by CMS to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart A—General Provisions

§ 417.1 Definitions.

As used in this part, unless the context indicates otherwise—

Basic health services means health services described in § 417.101(a).

Community rating system means a system of fixing rates of payments for health services that meets the requirements of § 417.104(a)(3).

Comprehensive health services means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 417.101(a)(1));

(2) Outpatient services and inpatient hospital services (§417.101(a)(2));

(3) Medically necessary emergency health services (§417.101(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§417.101(a)(6)).

Direct service contract means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

Enrollee means an individual for whom an HMO, CMP, or HCPP assumes the responsibility, under a contract or agreement, for the furnishing of health care services on a prepaid basis.

Full-time student means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Furnished, when used in connection with prepaid health care services, means services that are maid available to an enrollee either dierctly by, or under arrangements made by, the HMO, CMP, or HCPP.

Health maintenance organization (HMO) means a legal entity that provides or arranges for the provision of basic and supplemental health services to its enrollees in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the PHS Act and the regulations in subparts B and C of this part.

Health professionals means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

Individual practice association (IPA) means a partnership, association, corporation, or other legal entity that delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement must provide:

(1) That these health professionals will provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

Medical group means a partnership, association, corporation, or other group:

(1) That is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to enrollees of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of

major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby an enrollee's enrollment status is not known to the health professional who provides health services to the enrollee.

Medical group members means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Medically underserved population means the population of an urban or rural area as described in Sec. 417.912(d).

Nonmetropolitan area means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

Party in interest means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

Policymaking body of an HMO means a board of directors, governing body, or other body of individuals that has the authority to establish policy for the HMO.

Qualified HMO means an HMO found by CMS to be qualified within the meaning of section 1310 of the PHS Act and subpart D of this part.

Rural area means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, ''Number of Inhabitants,'' Table VI, ''Population of Places,'' and not listed as an urbanized area in Table XI, ''Population of Urbanized Areas'' of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b).

Significant business transaction means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

Staff of the HMO means health professionals who are employees of the HMO and who—

(1) Provide services to HMO enrollees at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to enrollees of the HMO the health services that the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO; and

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

Subscriber means an enrollee who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Supplemental health services means the health services described in §417.102(a).

Unusual or infrequently used health services means:

(1) Those health services that are projected to involve fewer than 1 percent of the encounters per year for the entire HMO enrollment, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987. Redesignated and amended at 56 FR 51985, Oct. 17, 1991; 58 FR 38067, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45674, Sept. 1, 1995]

§417.2 Basis and scope.

(a) Subparts B through F of this part pertain to the Federal qualification of HMOs under title XIII of the Public Health Service (PHS) Act.

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act.

(c) Subpart U of this part pertains to Medicare payment to health care prepayment plans under section 1833(a)(1)(A) of the Act.

(d) Subpart V of this part applies to the administration of outstanding loans and loan guarantees previously granted under title XIII of the PHS Act.

[56 FR 51985, Oct. 17, 1991, as amended at 60 FR 45675, Sept. 1, 1995]

Subpart B—Qualified Health Maintenance Organizations: Services

§417.101 Health benefits plan: Basic health services.

(a) An HMO must provide or arrange for the provision of basic health services to its enrollees as needed and without limitations as to time and cost other than those prescribed in the PHS Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which must be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which must include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital;

(ii) Inpatient hospital services, which must include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;

(iii) Outpatient services and inpatient hospital services must include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its enrollees on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per enrollee per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs must include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services must be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at an enrollee's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which must be made available to members and must include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 417.102 as a supplemental health service in the basic health services that it provides or arranges for its enrollees for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§ 417.101 through 417.106 and §§ 417.168 and 417.169, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the PHS Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the enrollee is legally entitled to services and for which facilities are reasonably available to this enrollee;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the PHS Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services that are unusual and infrequently provided and not necessary for the protection of individual health, as approved by CMS upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis that do not include all the basic health services set forth in paragraph (a) of this section or that are limited as to time and cost except in a manner prescribed by this subpart.

[45 FR 72528, Oct. 31, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38077, July 15, 1993]

§417.102 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its enrollees any health service that is not included as a basic health service under §417.101(a). These health services may be limited as to time and cost.

(b) An HMO must determine the level and scope of supplemental health services included with basic health services provided to its enrollees for a basic health services payment or those services offered to its enrollees as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.103 Providers of basic and supplemental health services.

(a)(1) The HMO must provide that the services of health professionals that are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, CMS approves the sharing as being consistent with the purposes of section 1310(b) of the PHS Act.

(3) After the 4 year period beginning with the month following the month in that an HMO becomes a qualified HMO, an entity that meets the requirements of the definition of medical group in §417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if CMS determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of CMS that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the ''substantial responsibility'' requirement of subdivision (3)(i) of the definition of ''medical group'' in §417.100. The HMO must update the plan annually and must demonstrate to the satisfaction of CMS that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of ''medical group,'' or

(ii) Demonstrating that compliance by the entity with the ''substantial responsibility'' requirement is unreasonable or impractical because (A) the HMO serves a non-metropolitan or rural area as defined in §417.100, or (B) the entity is a multi-speciality group that provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of enrollees to require utilization of at least 35 percent of the entity's services.

(b) HMOs must have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial

incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the enrollee other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services must be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO must:

(1) Pay the provider, or reimburse its enrollees for the payment of reasonable charges for basic health services (or supplemental health services that the HMO agreed to provide on a prepayment basis) for which its enrollees have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from enrollees for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its enrollees on procedures to be followed to secure these health services.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO must provide or arrange for the provision of basic health services for a basic health services payment that:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its enrollees, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or enrollment in the HMO, an HMO may not impose copayment charges on any subscriber (or enrollees covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or enrollees) in that calendar year total 200 percent of the total annual premium cost which that subscriber (or enrollees) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or enrollees) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an

HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates will be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue that would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers must be calculated to yield revenues substantially equivalent to the product of the total number of enrollees (or subscribers) expected to be enrolled from the group and the per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment that are established for new enrollments or re-enrollments and that do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates will be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it must:

(i) Classify all of the enrollees of the organization into classes based on factors that the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by CMS,

(ii) Determine its revenue requirements for providing services to the enrollees of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. CMS will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If CMS determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, CMS will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 (''Contracts for Medical Care for Spouses and Children: Plans'') or section 1086 (''Contracts for Health Benefits for Certain Members, Former Members and their Dependents'') of title 10 (''Armed Forces''), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 (''Health Insurance'') of title 5 (''Government Organization and Employees''), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to CMS of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its enrollees, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided an enrollee who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable that are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*[1] An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915–0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

§ 417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning

[1] Further information entitled ''Guidelines for Rating by Class'' may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

with the month following the month in which it became a qualifed HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.

(a) *Quality assurance program.* Each HMO or CMP must have an ongoing quality assurance program for its health services that meets the following conditions:

(1) Stresses health outcomes to the extent consistent with the state of the art.

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services.

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change.

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.

(b) *Availability and accessibility of health care services.* Basic health services and those supplemental health services for which enrollees have contracted must be provided or arranged for by the HMO in accordance with the following rules:

(1) Except as provided in paragraph (b)(2) of this section, the services must be available to each enrollee within the HMO's service area.

(2) *Exception.* If the HMO's service area is located wholly within a nonmetropolitan area, the HMO may make available outside its service area any basic health service that is not a primary care or emergency care service, if the number of providers of that basic health service who will provide the service to the HMO's enrollees is insufficient to meet the demand. As used in this paragraph, primary care includes general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO that provides the services covered by these fields through at least a general or family practitioner, or a pediatrician and a general internist, is considered to be providing primary care.

(3) The services must be available and accessible with reasonable promptness to each of the HMO's enrollees as ensured through—

(i) Staffing patterns within generally accepted norms for meeting the projected enrollment needs; and

(ii) Geographic location, hours of operation, and arrangements for afterhours services. (Medically necessary emergency services must be available 24 hours a day, 7 days a week.)

(c) *Continuity of care.* The HMO must ensure continuity or care through arrangements that include but are not limited to the following:

(1) Use of a health professional who is primarily responsible for coordinating the enrollee's overall health care.

(2) A system of health and medical records that accumulates pertinent information about the enrollee's health care and makes it available to appropriate professionals.

(3) Arrangements made directly or through the HMO's providers to ensure that the HMO or the health professional who coordinates the enrollee's overall health care is kept informed about the services that the referral resources furnish to the enrollee.

(d) *Confidentiality of health records.* Each HMO must establish adequate procedures to ensure the confidentiality of the health and medical records of its enrollees.

[58 FR 38068, July 15, 1993]

Subpart C—Qualified Health Maintenance Organizations: Organization and Operation

SOURCE: 58 FR 38068, July 15, 1993, unless otherwise noted.

§ 417.120 Fiscally sound operation and assumption of financial risk.

(a) *Fiscally sound operation*—(1) *General requirements.* Each HMO must have a fiscally sound operation, as demonstrated by the following:

(i) Total assets greater than total unsubordinated liabilities. In evaluating assets and liabilities, loan funds awarded or guaranteed under section 1306 of the PHS Act are not included as liabilities.

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(iii) A net operating surplus, or a financial plan that meets the requirements of paragraph (a)(2) of this section.

(iv) An insolvency protection plan that meets the requirements of § 417.122(b) for protection of enrollees.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO.

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by CMS to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(2) *Financial plan requirement.* (i) If an HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year or does not have positive net worth, the HMO must submit a financial plan satisfactory to CMS to achieve net operating surplus within available fiscal resources.

(ii) This plan must include—

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds statements; and

(D) Balance sheets.

(b) *Assumption of financial risk.* Each HMO must assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements as follows:

(1) For the cost of providing to any enrollee basic health services with an aggregate value of more than $5,000 in any year.

(2) For the cost of basic health services obtained by its enrollees from sources other than the HMO because medical necessity required that they be furnished before they could be secured through the HMO.

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(4) For physicians or other health professionals, health care institutions, or any other combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for their furnishing of basic health services to the HMO's enrollees.

§ 417.122 Protection of enrollees.

(a) *Liability protection.* (1) Each HMO must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the HMO. These arrangements may include any of the following:

(i) Contractual arrangements that prohibit health care providers used by the enrollees from holding any enrollee liable for payment of any fees that are the legal obligation of the HMO.

(ii) Insurance, acceptable to CMS.

(iii) Financial reserves, acceptable to CMS, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to CMS.

(2) The requirements of this paragraph do not apply to an HMO if CMS determines that State law protects the HMO enrollees from liability for payment of any fees that are the legal obligation of the HMO.

(b) *Protection against loss of benefits if the HMO becomes insolvent.* The insolvency protection plan required under § 417.120(a) must provide for continuation of benefits as follows:

(1) For all enrollees, for the duration of the contract period for which payment has been made.

(2) For enrollees who are in an inpatient facility on the date of insolvency, until they are discharged from the facility.

§417.124 Administration and management.

(a) *General requirements.* Each HMO must have administrative and managerial arrangements satisfactory to CMS, as demonstrated by at least the following:

(1) A policymaking body that exercises oversight and control over the HMO's policies and personnel to ensure that management actions are in the best interest of the HMO and its enrollees.

(2) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO.

(3) At a minimum, management by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Full and fair disclosure*—(1) *Basic rule.* Each HMO must prepare a written description of the following:

(i) Benefits (including limitations and exclusions).

(ii) Coverage (including a statement of conditions on eligibility for benefits).

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied.

(iv) Rates.

(v) Grievance procedures.

(vi) Service area.

(vii) Participating providers.

(viii) Financial condition including at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Requirements for the description.* (i) The description must be written in a way that can be easily understood by the average person who might enroll in the HMO.

(ii) The description of benefits and coverage may be in general terms if reference is made to a detailed statement of benefits and coverage that is available without cost to any person who enrolls in the HMO or to whom the opportunity for enrollment is offered.

(iii) The HMO must provide the description to any enrollee or person who is eligible to elect the HMO option and who requests the material from the HMO or the administrator of a health benefits plan. For purposes of this requirement, ''administrator'' (of a health benefits plan) has the meaning it is given in the Employment Retirement Income Security Act of 1974 (ERISA) at 29 U.S.C. 1002(16)(A).

(iv) If the HMO provides health services through individual practice associations (IPAs), the HMO must specify the number of member physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(v) If the HMO provides health services other than through IPAs, the HMO must specify, for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(c) *Broadly representative enrollment.* (1) Each HMO must offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area.

(2) If an HMO has a medically underserved population located in its service area, not more than 75 percent of its enrollees may be from the medically underserved population unless the area in which that population resides is a rural area.

(d) *Health status and enrollment.* (1) The HMO may not, on the basis of health status, health care needs, or age of the individual—

(i) Expel or refuse to reenroll any enrollee; or

(ii) Refuse to enroll individual members of a group.

(2) For purposes of this paragraph, a ''group'' is composed of individuals who enroll in the HMO under a contract or other arrangement that covers two or more subscribers. Examples of groups are employees who enroll under a contract between their employer and the HMO, or members of an organization

that arranges coverage for its membership.

(3) Nothing in this subpart prohibits an HMO from requiring that, as a condition for continued eligibility for enrollment, enrolled dependent children, upon reaching a specified age, convert to individual enrollment, consistent with paragraph (e) of this section.

(e) *Conversion of enrollment.* (1) Each HMO must offer individual enrollment to the following:

(i) Each enrollee (and his or her enrolled dependents) leaving a group.

(ii) Each enrollee who would otherwise cease to be eligible for HMO enrollment because of his or her age, or the death or divorce of an enrollee.

(2) The individual enrollment offered must meet the conditions of subpart B of this part and this subpart C.

(3) The HMO is not required to offer individual enrollment except to the enrollees specified in this paragraph.

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

(f) [Reserved]

(g) *Grievance procedures.* Each HMO must have and use meaningful procedures for hearing and resolving grievances between the HMO's enrollees and the HMO, including the HMO staff and medical groups and IPAs that furnish services. These procedures must ensure that:

(1) Grievances and complaints are transmitted in a timely manner to appropriate HMO decisionmaking levels that have authority to take corrective action; and

(2) Appropriate action is taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Certification of institutional providers.* Each HMO must ensure that its affiliated institutional providers meet one of the following conditions:

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by CMS in accordance with section 353 of the PHS Act and part 493 of this chapter:

(i) Registration certificate.

(ii) Certificate.

(iii) Certificate of waiver.

(iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

§ 417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the HMO has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each HMO must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *''Significant business transaction'' defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

(i) Sale, exchange or lease of property.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(i) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may

waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

Subpart D—Application for Federal Qualification

§ 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) Qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that CMS follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

§ 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.

(2) CMS determines whether the entity is an HMO on the basis of the entity's application and any additional information and investigation (including site visits) that CMS may require.

(3) CMS may determine that an entity is any of the following:

(i) An operational qualified HMO.

(ii) A preoperational qualified HMO.

(iii) A transitional qualified HMO.

(b) *Operational qualified HMO.* CMS determines that an entity is an operational qualified HMO if—

(1) CMS finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of CMS's determination, provides written assurances, satisfactory to CMS, that it—

(i) Provides and will provide basic health services (and any supplemental health services included in any contract) to its enrollees;

(ii) Provides and will provide these services in the manner prescribed in sections 1301(b) and 1301(c) of the PHS Act and subpart B of this part;

(iii) Is organized and operated and will continue to be organized and operated in the manner prescribed in section 1301(c) of the PHS Act and subpart C of this part;

(iv) Under arrangements that safeguard the confidentiality of patient information and records, will provide access to CMS and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operation as an HMO, and to any facilities that it operates; and

(v) Will continue to comply with any other assurances that it has given to CMS.

(c) *Preoperational qualified HMO.* (1) CMS may determine that an entity is a preoperational qualified HMO if it provides, within 30 days of CMS's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of subparts B and C of this part.

(2) Within 30 days after receiving notice that the entity has begun operation, CMS determines whether it is an operational qualified HMO. In the absence of this determination, the entity is not an operational qualified HMO even though it becomes operational.

(d) *Transitional qualified HMO: General rules*—(1) *Basic requirements.* CMS may determine that an entity is a transitional qualified HMO if the entity—

(i) Meets the requirements of paragraph (d)(2) through (d)(4) of this section; and

(ii) Provides the assurances specified in paragraphs (d)(5) through (d)(7) of this section within 30 days of CMS's determination.

(2) *Organization and operation.* The entity is organized and operated in accordance with subpart C of this part, except that it need not—

(i) Assume full financial risk for the provision of basic health services as required by §417.120(b); or

(ii) Comply with the limitations that are imposed on insurance by §417.120(b)(1).

(3) *Range of services.* The entity is currently providing the following services on a prepaid basis:

(i) Physician services.

(ii) Outpatient services and inpatient hospital services. (The entity need not provide or pay for hospital inpatient or outpatient services that it can show are being provided directly, through insurance, or under arrangements, by other entities.)

(iii) Medically necessary emergency services.

(iv) Diagnostic laboratory services and diagnostic and therapeutic radiologic services.

These services must meet the requirement of §417.101, but may be limited in time and cost without regard to the constraints imposed by §417.101(a).

(4) *Payment for services*—(i) *General rule.* The entity pays for basic health services in accordance with §417.104, except that it need not comply with the copayments limitations imposed by §417.104(a)(4).

(ii) *Determination of payment rates.* In determining payment rates, the entity need not comply with the community rating requirements of §§417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of CMS's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of CMS's determination, and which are renewed or renegotiated during the period approved by CMS under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to CMS that—

(A) May not extend for more than 3 years from the date of CMS's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of CMS's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of CMS's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If CMS determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, CMS gives the entity written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

[59 FR 49836, Sept. 30, 1994]

§ 417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.* (1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by CMS.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the PHS Act and in subparts B and C of this part, this subpart D, and 417.168 and 417.169 of subpart F.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, CMS determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) $18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, CMS determines that there is no need for a site visit, $8,000 will be returned to the applicant.

(2) $6,900 for an HMO seeking expansion of its service area.

(3) $3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* CMS refunds an application fee only if the entity withdraws its application within 10 working days after receipt by CMS. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If CMS determines that a change in the amount of a fee is appropriate, CMS issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under this subpart for the same type of determination for four full months after the date of the notice in which CMS denied the application.

(h) *Disclosure of application information under the Freedom of Information*

Act. An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993]

§417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that CMS obtains through onsite visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the entity meets the applicable requirements of §§417.142 and 417.143.

(b) *Notice of determination*. CMS notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny*. (1) If CMS finds that the entity does not appear to meet the requirements for qualification and appears to be able to meet those requirements within 60 days, CMS gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding, and may revise its application to remedy any defects identified by CMS.

(d) *Denial and reconsideration of denial*. (1) If CMS denies an application for qualification under this subpart, CMS gives the entity written notice of the denial and an opportunity to request reconsideration of that determination.

(2) A request for reconsideration must—

(i) Be submitted in writing, within 60 days following the date of the notice of denial;

(ii) Be addressed to the CMS officer or employee who denied the application; and

(iii) Set forth the grounds upon which the entity requests reconsideration, specifying the material issues of fact and of law upon which the entity relies.

(3) CMS bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to CMS.

(4) CMS gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs*—(1) FEDERAL REGISTER *notices*. In quarterly FEDERAL REGISTER notices, CMS gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings*. A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, room 4360, Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

[59 FR 49837, Sept. 30, 1994]

Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.150 Definitions.

As used in this subpart, unless the context indicates otherwise—

Agreement means a collective bargaining agreement.

Bargaining representative means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

Carrier means a voluntary association, corporation, partnership, or other organization that is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, enrollment or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

Collective bargaining agreement means an agreement entered into between an employing entity and the bargaining representative of its employees.

Contract means an employer-employee or public entity-employee contract, or a contract for health benefits.

Designee means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of enrollment in a qualified health maintenance organization to their eligible employees.

Eligible employee means an employee who meets the employer's requirements for participation in the health benefits plan.

Employee means any individual employed by an employer or public entity on a full-time or part-time basis.

Employer has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

Employing entity means an employer or public entity.

Employing entity-employee contract means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

Group enrollment period means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

Health benefits contract means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

Health benefits plan means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

Public entity means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

Qualified HMO means an HMO that has in effect a determination, made

under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

To offer a health benefits plan means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through payments on any basis into a health and welfare trust fund.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993; 59 FR 49837, 49843, Sept. 30, 1994]

§417.151 Applicability.

(a) *Basic rule.* Effective October 24, 1995,[1] this subpart applies to any employing entity that offers a health benefits plan to its employees, meets the conditions specified in paragraphs (b) through (e) of this section, and elects to include one or more qualified HMOs in the health plan alternatives it offers its employees.

(b) *Number of employees.* During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage.* During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act.* The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Employees in HMO's service area.* At least 25 of the employing entity's employees reside within the HMO's service area.

[59 FR 49838, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

§417.153 Offer of HMO alternative.

(a) *Basic rule.* An employing entity that is subject to this subpart and that elects to include one or more qualified HMOs must offer the HMO alternative in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option.* (1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO—

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

[59 FR 49839, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

§417.155 How the HMO option must be included in the health benefits plan.

(a) *HMO access to employees*—(1) *Purpose and timing*—(i) *Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in §417.153(b), so that the HMO can explain its program in accordance with §417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of §417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other

[1] Before October 24, 1995, an employing entity that met the conditions specified in §417.151 was required to include one or more qualified HMOs, if it received from at least one qualified HMO a written request for inclusion and that request met the timing, content, and procedural requirements specified in §417.152.

offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* (1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage*—(1) *Prohibition of restrictions.* If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for ''free-standing'' health benefits*—(1) *Basic requirement.* At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *''Free-standing'' defined.* For purposes of this paragraph, the term ''free-standing'' refers to a benefit that—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option

continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection*—(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

(i) Are required to be offered under State law.

(ii) Are included uniformly by the HMO in its prepaid benefit package.

(iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

[59 FR 49840, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§417.156 When the HMO must be offered to employees.

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

(i) When a new agreement is negotiated;

(ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or

(iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee

must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the contract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

(i) At the time each contract or arrangement is renewed or reissued; or

(ii) The benefits provided under the contract or arrangement are offered to employees.

[59 FR 49841, Sept. 30, 1994]

§ 417.157 Contributions for the HMO alternative.

(a) *General principles*—(1) *Nondiscrimination.* The employer contribution to an HMO must be in an amount that does not discriminate financially against an employee who enrolls in an HMO. A contribution does not discriminate financially if the method of determining the contribution is reasonable and is designed to ensure that employees have a fair choice among health benefits plan alternatives.

(2) *Effect of agreements or contracts.* The employing entity or designee is not required to pay more for health benefits as a result of offering the HMO alternative than it would otherwise be required to pay under a collective bargaining agreement or contract that provides for health benefits and is in effect at the time the HMO alternative is included.

(3) *Examples of acceptable employer contributions.* The following are methods that are considered nondiscriminatory:

(i) The employer contribution to the HMO is the same, per employee, as the contribution to non-HMO alternatives.

(ii) The employer contribution reflects the composition of the HMO's enrollment in terms of enrollee attributes that can reasonably be used to predict utilization, experience, costs, or risk. For each enrollee in a given class established on the basis of those attributes, the employer contributes an equal amount, regardless of the health benefits plan chosen by the employee.

(iii) The employer contribution is a fixed percentage of the premium for each of the alternatives offered.

(iv) The employer contribution is determined under a mutually acceptable arrangement negotiated by the HMO and the employer. In negotiating the arrangement, the employer may not insist on terms that would cause the HMO to violate any of the requirements of this part.

(4) *Adjustment of employer contribution.* An employer contribution determined by an acceptable method may in some cases be adjusted if it would result in a nominal payment or no payment at all by HMO enrollees (because the HMO premium is lower than the premiums for the other alternatives offered). If, for example the employer has a policy of requiring all employees to contribute to their health benefits plan, the employer may require HMO enrollees who would otherwise pay little or nothing at all, to make a payment that does not exceed 50 percent of the employee contribution to the principal non-HMO alternative. The principal non-HMO alternative is the one that covers the largest number of enrollees from the particular employer.

(b) *Administrative expenses.* (1) In determining the amount of its contribution to the HMO, the employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan.

(2) However, if the employing entity or designee has special requirements for other than standard solicitation brochures and enrollment literature, it must, in the case of the HMO alternative, determine and distribute any administrative costs attributable to those requirements in a manner consistent with its method of determining

and distributing those costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or the designee's cost for the HMO alternative, the employing entity or designee may exclude those portions of the contribution allocable to benefits (such as life insurance or insurance for supplemental health benefits)—

(1) For which eligible employees and their eligible dependents are covered notwithstanding selection of the HMO alternative; and

(2) That are not offered on a prepayment basis by the HMO to the employing entity's employees.

(d) *Contributions determined by agreements or contracts or by law.* If the specific amount of the employing entity's contribution for health benefits is fixed by an agreement or contract, or by law, that amount constitutes the employing entity's obligation for contribution toward the HMO premiums.

(e) *Allocation of portion of a contribution determined by an agreement.* In some cases, the employing entity's contribution for health benefits is determined by an agreement that also provides for benefits other than health benefits. In that case, the employing entity must determine, or instruct its designee to determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to CMS upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *CMS review of data.* (1) CMS may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of CMS's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request CMS to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

§417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

§417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.160 Applicability.

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

§417.161 Compliance with assurances.

Any entity subject to this subpart must comply with the assurances that it provided to CMS, unless compliance is waived under §417.166.

[58 FR 38071, July 15, 1993]

§ 417.162 Reporting requirements.

Entities subject to this subpart must submit:

(a) The reports that may be required by CMS under § 417.126, and

(b) Any additional reports CMS may reasonably require.

[58 FR 38071, July 15, 1993]

§ 417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with CMS a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) CMS may initiate investigations when, based on a report, a complaint, or any other information, CMS has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When CMS initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) CMS obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that CMS considers appropriate in seeking this information.

(c) *Determination and notice by CMS*—(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by CMS in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for CMS's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If CMS determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—

(1) CMS revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, CMS provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day after the day of the notice unless CMS receives a request for reconsideration by that date.

(4) If after reconsideration CMS again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) CMS publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in § 417.164.

(e) *Notice by the HMO.* Within 15 days after the date CMS issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§417.104 and 417.105. The additional rules applicable to Medicare enrollees are in §415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under §417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under §417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§417.166 Waiver of assurances.

(a) *General rule.* CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the

HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subparts G–I [Reserved]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

§ 417.401 Definitions.

As used in this subpart and subparts K through R of this part, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by CMS in advance of an HMO's or CMP's contract period that represents what the average per capita cost to the Medicare program would be for each class of the HMO's or CMP's Medicare enrollees if they had received covered services other than through the HMO or CMP in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk HMO or CMP would charge Medicare enrollees independently of Medicare payments if the HMO or CMP used the same rates it charges non-Medicare enrollees for a benefit package limited to covered Medicare services.

Arrangement means a written agreement between an HMO or CMP and another entity, under which—

(1) The other entity agrees to furnish specified services to the HMO's or CMP's Medicare enrollees;

(2) The HMO or CMP retains responsibility for the services; and

(3) Medicare payment to the HMO or CMP discharges the beneficiary's obligation to pay for the services.

Benefit stabilization fund means a fund established by CMS, at the request of a risk HMO or CMP, to withhold a portion of the per capita payments available to the HMO or CMP and pay that portion in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits the HMO or CMP provides to its Medicare enrollees.

Cost contract means a Medicare contract under which CMS pays the HMO or CMP on a reasonable cost basis.

Cost HMO or CMP means an HMO or CMP that has in effect a cost contract with CMS under section 1876 of the Act and subpart L of this part.

Demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source other than the HMO or CMP and that meet the following conditions:

(1) Are needed immediately because of an injury or sudden illness.

(2) Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health

or because transfer would be unreasonable, given the distance and the nature of the medical condition.

Geographic area means the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means a Medicare beneficiary who has been identified on CMS records as an enrollee of an HMO or CMP that has a contract with CMS under section 1876 of the Act and subpart L of this part.

New Medicare enrollee means a Medicare beneficiary who—

(1) Enrolls with an HMO or CMP after the date on which the HMO or CMP first enters into a risk contract under subpart L of this part; and

(2) Was not enrolled with the HMO or CMP at the time he or she became entitled to benefits under Part A or eligible to enroll in Part B of Medicare.

Risk contract means a Medicare contract under which CMS pays the HMO or CMP on a risk basis for Medicare covered services.

Risk HMO or CMP means an HMO or CMP that has in effect a risk contract with CMS under section 1876 of the Act and subpart L of this part.

Urgently needed services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that—

(1) Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

(2) Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 51986, Oct. 17, 1991; 58 FR 38072, July 15, 1993; 60 FR 45675, Sept. 1, 1995]

§417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in §417.492(b) and §417.494(a) for any period beginning on or after January 1, 2013, where—

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000.

[63 FR 35066, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4713, Jan. 28, 2005; 73 FR 54248, Sept. 18, 2008; 76 FR 21560, Apr. 15, 2011; 76 FR 54633, Sept. 1, 2011]

§ 417.404 General requirements.

(a) In order to contract with CMS under the Medicare program, an entity must—

(1) Be determined by CMS to be an HMO or CMP (in accordance with §§ 117.142 and 417.407, respectively); and

(2) Comply with the contract requirements set forth in subpart L of this part.

(b) CMS enters into or renews a contract only if it determines that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

[60 FR 45675, Sept. 1, 1995]

§ 417.406 Application and determination.

(a) *Responsibility for making determinations.* CMS is responsible for determining whether an entity meets the requirements to be an HMO or CMP.

(b) *Application requirements.* (1) The application requirements for HMOs are set forth in § 417.143.

(2) The requirements of § 417.143 also apply to CMPs except that there are no application fees.

(c) *Determination.* CMS uses the procedures set forth in § 417.144(a) through (d) to determine whether an entity is an HMO or CMP.

(d) *Oversight of continuing compliance.* (1) CMS oversees an entity's continued compliance with the requirements for an HMO as defined in § 417.1 or for a CMP as set forth in § 417.407.

(2) If an entity no longer meets those requirements, CMS terminates the contract of that entity in accordance with § 417.494.

[60 FR 45675, Sept. 1, 1995]

§ 417.407 Requirements for a Competitive Medical Plan (CMP).

(a) *General rule.* To qualify as a CMP, an entity must be organized under the laws of a State and must meet the requirements of paragraphs (b) through (f) of this section.

(b) *Required services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, the entity furnishes to its enrollees at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, x-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) Exception for Medicaid prepayment risk contracts. An entity that had, before 1970, a Medicaid prepayment risk contract that did not include provision of inpatient hospital services is not required to provide those services.

(c) *Compensation for services.* The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrollees on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any enrollee.

(d) *Source of physicians' services.* The entity provides physicians' services primarily through—

(1) Physicians who are employees or partners of the entity; or

(2) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(e) *Assumption of financial risk.* The rules set forth in § 417.120(b) for HMOs apply also to CMPs except that reference to ''basic services'' must be read as reference to the required services listed in paragraph (b) of this section.

(f) *Protection of enrollees.* The entity provides adequately against the risk of insolvency by meeting the requirements of §§ 417.120(a) and 417.122 for protection of enrollees against loss of benefits and liability for payment of any fees that are the legal responsibility of the entity.

[60 FR 45675, Sept. 1, 1995]

§ 417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by CMS. (2) Whenever feasible, CMS exempts the HMO or CMP from resubmittal of information it has already submitted to CMS in connection with a determination made under the provisions of § 417.406.

(b) *Approval of application.* (1) If CMS approves the application, it gives written notice to the HMO or CMP, indicating that it meets the requirements

for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the HMO or CMP is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in subpart R of this part.

(c) *Denial of application.* If CMS denies the application, it gives written notice to the HMO or CMP indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the HMO or CMP does not meet the contract requirements; and

(3) The HMO's or CMP's right to request reconsideration in accordance with the procedures specified in subpart R of this part.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.410 Qualifying conditions: General rules.

(a) *Basic requirement.* In order to qualify for a contract with CMS under this subpart, an HMO or CMP must demonstrate its ability to enroll Medicare beneficiaries and other individuals and groups and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) *Other qualifying conditions.* An HMO or CMP must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

(c) *Standards.* Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an HMO or CMP to determine its qualifications for a Medicare contract.

(d) *Application of standards.* Application of the standards enables the surveyor to determine—

(1) The HMO's or CMP's activities;

(2) The extent to which the HMO or CMP complies with each condition;

(3) The nature and extent of any deficiencies; and

(4) The need for improvement if CMS should enter into a contract with the HMO or CMP.

(e) *Requirements for a risk contract.* An HMO or CMP may enter into a risk contract with CMS if it—

(1) Meets all the applicable requirements in the statute and regulations;

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in §417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies CMS that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost sontract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

(1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

(a) Has sufficient administrative capability to carry out the requirements of the contract; and

(b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid beneficiaries constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid beneficiaries in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or ''accreted'' to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section. CMS may decline to renew an HMO's or CMP's contract in accordance with §417.492(b), or terminate its contract in accordance with §417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid beneficiaries (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be ''substantially nonrepresentative'' if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in §417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs*—(1)

Basic requirement. Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.* (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in § 417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision.* The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement.* The following services may

be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in § 491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§ 405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in § 410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a clinical social worker (as defined at § 410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a clinical social worker (as defined in § 410.73 of this chapter). Services incident to the professional services of a clinical social worker furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity.* (1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The HMO or CMP must maintain a health (including medical) record-keeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 20130, Apr. 23, 1998]

§ 417.418 Qualifying condition: Quality assurance program.

(a) *Condition.* The HMO or CMP must make arrangements for a quality assurance program that meets the requirements of this section.

(b) *Standard.* An HMO or CMP must have an ongoing quality assurance program that meets the requirements set forth in § 417.106(a).

[58 FR 38072, July 15, 1993]

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.420 Basic rules on enrollment and entitlement.

(a) *Enrollment.* Individuals who are entitled to benefits under both Part A and Part B of Medicare or only Part B may elect to receive those benefits through an HMO or CMP that has in effect a contract with CMS under subpart L of this part.

(b) *Entitlement.* If a Medicare beneficiary enrolls with an HMO or CMP, CMS pays the HMO or CMP on his or her behalf for the services to which he or she is entitled.

(c) *Beneficiary liability.* (1) The HMO or CMP may require payment, in the form of premiums or otherwise, from individuals for services not covered under Medicare, as well as deductible and coinsurance amounts attributable to Medicare covered services.

(2) As described in § 417.448, Medicare enrollees of risk HMOs or CMPs are liable for services that they obtain from sources other than the HMO or CMP, unless the services are—

(i) Emergency or urgently needed; or

(ii) Determined, on appeal under subpart Q of this part, to be services that should have been furnished by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.422 Eligibility to enroll in an HMO or CMP.

Except as specified in §§ 417.423 and 417.424, an HMO or CMP must enroll,

either for an indefinite period or for a specified period of at least 12 months, any individual who—

(a) Is entitled to Medicare benefits under Parts A and B or under Part B only;

(b) Lives within the geographic area served by the HMO or CMP;

(c) Is not enrolled in any other HMO or CMP that has entered into a contract under subpart L of this part;

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment;

(e) Agrees to abide by the HMO's or CMP's rules after they are disclosed to him or her in connection with the enrollment process;

(f) Is not denied enrollment by the HMO or CMP under a selection policy, if any, that has been approved by CMS under § 417.424(b); and

(g) Is not denied enrollment by the HMO or CMP on the basis of any of the administrative criteria concerning denial of enrollment in § 417.424(a).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012]

§ 417.423 Special rules: ESRD and hospice patients.

(a) *ESRD patients.* (1) A Medicare beneficiary who has been medically determined to have end-stage renal disease is not eligible to enroll in an HMO or CMP.

(2) However, if a beneficiary is already enrolled in an HMO or CMP when he or she is determined to have end-stage renal disease, the HMO or CMP—

(i) Must reenroll the beneficiary as required by § 417.434; and

(ii) May not disenroll the beneficiary except as provided in § 417.460.

(b) *Hospice patients.* A Medicare beneficiary who elects hospice care under § 418.24 of this chapter is not eligible to enroll in an HMO or CMP as long as the hospice election remains in effect.

[60 FR 45677, Sept. 1, 1995]

§ 417.424 Denial of enrollment.

(a) *Basis for denial.* An HMO or CMP may deny enrollment to an individual who meets the criteria of § 417.422 if acceptance would—

(1) Cause the number of enrollees who are Medicare or Medicaid beneficiaries to exceed 50 percent of the HMO's or CMP's total enrollment;

(2) Prevent the HMO or CMP from complying with any of the other contract qualifying conditions set forth in subpart J of this part;

(3) Require the HMO or CMP to exceed its enrollment capacity; or

(4) Cause the enrollment to become substantially nonrepresentative of the general population in the HMO's or CMP's geographic area.

(b) *Selection policies.* (1) Denial under paragraph (a)(4) of this section must be in accordance with written selection policies approved by CMS. (2) Enrollment of individuals will not be considered to make the enrollment of the HMO or CMP substantially nonrepresentative of the general population in the HMO's or CMP's geographic area unless, as a result of the enrollment, the proportion of the subgroup of enrollees to which the enrollee belongs as compared to the HMO's or CMP's total enrollment exceeds by at least ten percent the subgroup's proportion of the general population in the geographic area of the HMO or CMP. (A subgroup is a class of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.)

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* (1) HMOs or CMPs must provide open enrollment for Medicare beneficiaries for at least 30 consecutive days during each contract year.

(2) During open enrollment, the HMO or CMP must enroll eligible Medicare beneficiaries in the order in which their applications are received and until its enrollment capacity is reached.

(3) The HMO or CMP may accept applications from Medicare beneficiaries after it has reached capacity if it places those individuals on a waiting list and enrolls them in chronological order as vacancies occur.

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

(b) *Capacity to accept new enrollees.* (1) If an HMO or CMP chooses to limit enrollments because of its capacity, it must notify CMS at least 90 days before the beginning of its open enrollment period and, at that time, provide CMS with its reasons for limiting enrollment.

(2) CMS evaluates the HMO's or CMP's submittal under paragraph (b)(1) of this section.

(3) The HMO or CMP must promptly notify CMS if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* (1) Subject to CMS's approval, an HMO or CMP may set aside a reasonable number of vacancies for an anticipated new group contract or for anticipated new enrollees under an existing group contract that will have its enrollment period after the Medicare open enrollment period during the contract year.

(2) Any set aside vacancies that are not filled within a reasonable time after the beginning of the group contract enrollment period must be made available to Medicare beneficiaries and other nongroup applicants under the requirements of this subpart.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.427 Extending MA and Part D program disclosure requirements to section 1876 cost contract plans.

(a) The procedures and requirements relating to disclosure in §422.111 and §423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of §§422.111 and 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

[77 FR 22166, Apr. 12, 2012]

§417.428 Marketing activities.

(a) With the exception of §422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

[75 FR 19802, Apr. 15, 2010]

§417.430 Application procedures.

(a) *Application forms and other enrollment mechanisms.* (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between the HHS and its designees and the HMO or CMP.

(2) The HMO or CMP must file and retain application forms for the period specified in CMS instructions.

(b) *Handling of applications.* An HMO or CMP must have an effective system for receiving, controlling, and processing applications from Medicare beneficiaries. The system must meet the following conditions and requirements:

(1) Each application is dated as of the day it is received.

(2) Applications are processed in chronological order by date of receipt.

(3) The HMO or CMP gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) The notice of acceptance. If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) The notice of denial explains the reason for denial.

(6) The HMO or CMP transmits the information necessary for CMS to add the beneficiary to its records of the HMO's or CMP's Medicare enrollees—

(i) Within 30 days from the date of application or from the date a vacancy occurs for an applicant who was accepted (for future enrollment) while there were no vacancies; or

(ii) Within an additional period of time approved by CMS on a showing by the HMO or CMP that it needs more time.

(7) The HMO or CMP promptly notifies the beneficiary of the effective month of his or her enrollment as a Medicare enrollee, when it receives that information from CMS.

(8) If the HMO or CMP accepts applications while it is enrolled to capacity, its procedures ensure that vacancies are filled in chronological order by date of application of beneficiaries who are still eligible to enroll, unless that would result in failure to comply with any of the qualifying conditions set forth in § 417.413.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 76 FR 21560, Apr. 15, 2011]

§ 417.432 Conversion of enrollment.

(a) *Basic rule.* An HMO or CMP must accept as a Medicare enrollee any individual who is enrolled in the HMO or CMP for the month immediately before the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(b) *Effective date of conversion.* Unless the individual chooses to disenroll from the HMO or CMP the individual's conversion to a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(c) *Prohibition against disenrollment.* An HMO or CMP may not disenroll an individual who is converting under the provisions of paragraph (a) of this section unless one of the conditions specified in § 417.460 is met.

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in § 417.430(a).

(e) *Expedited submittal of information to CMS.* The HMO or CMP must notify CMS, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for CMS to include the enrollee in its records as a Medicare enrollee of the HMO or CMP:

(1) At least 30, but no earlier than 90, days before the enrollee—

(i) Attains age 65; or

(ii) Reaches his or her 25th month of entitlement to social security disability benefits under title II of the Act or railroad retirement disability benefits under section 7(d) of the Railroad Retirement Act of 1974.

(2) Within 30 days after the enrollee initiates a course of renal dialysis, or on or before the day he or she enters a hospital in anticipation of a kidney transplant.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012]

§ 417.434 Reenrollment.

If an HMO or CMP requires periodic reenrollment, it must reenroll Medicare enrollees unless there is a basis for disenrollment as set forth in § 417.460.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.436 Rules for enrollees.

(a) *Maintaining rules.* An HMO or CMP must maintain written rules that deal with, but need not be limited to the following:

(1) All benefits provided under the contract, as described in § 417.440.

(2) How and where to obtain services from or through the HMO or CMP.

(3) The restrictions on coverage for services furnished from sources outside a risk HMO or CMP, other than emergency services and urgently needed services (as defined in § 417.401).

(4) The obligation of the HMO or CMP to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services as required by § 417.414(c).

(5) Any services other than the emergency or urgently needed services that the HMO or CMP chooses to provide as permitted by this part, from sources outside the HMO or CMP. A cost HMO or CMP must disclose that the enrollee may receive services through any Medicare providers and suppliers.

(6) Premium information, including the amount (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable.

(7) Grievance and appeal procedures.

(8) Disenrollment rights.

(9) The obligation of an enrollee who is leaving the HMO's or CMP's geographic area for more than 90 days to notify the HMO or CMP of the move or extended absence and the HMO's or CMP's policies concerning retention of enrollees who leave the geographic area for more than 90 days, as described in §417.460(a)(2).

(10) The expiration date of the Medicare contract with CMS and notice that both CMS and the HMO or CMP are authorized by law to terminate or refuse to renew the contract, and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the HMO or CMP.

(11) Advance directives as specified in paragraph (d) of this section.

(12) Any other matters that CMS may prescribe.

(b) *Availability of rules.* The HMO or CMP must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter.

(c) *Changes in rules.* If an HMO or CMP changes its rules, it must submit the changes to CMS in accordance with §417.428(a)(3), and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

(d) *Advance directives.* (1) An HMO or CMP must maintain written policies and procedures concerning advance directives, as defined in §489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

(*1*) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(*2*) Identify the state legal authority permitting such objection; and

(*3*) Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency.

[58 FR 38072, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994; 60 FR 33292, June 27, 1995]

§ 417.440 Entitlement to health care services from an HMO or CMP.

(a) *Basic rules.* (1) Subject to the conditions and limitations set forth in this subpart, a Medicare enrollee of an HMO or CMP is entitled to receive health care services and supplies directly from, or through arrangements made by, the HMO or CMP as specified in this section and §§ 417.442–417.446.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services are—

(i) Emergency services or urgently needed services as defined § 417.401;

(ii) Services denied by the HMO or CMP and found (upon appeal under subpart Q of this part) to be services the enrollee was entitled to have furnished by the HMO or CMP.

(b) *Scope of services*—(1) *Part A and Part B services.* Except as specified in paragraphs (c), (d), and (e) of this section, a Medicare enrollee is entitled to receive from an HMO or CMP all the Medicare-covered services that are available to individuals residing in the HMO's or CMP's geographic area, as follows:

(i) Medicare Part A and Part B services if the enrollee is entitled to benefits under both programs.

(ii) Medicare Part B services if the enrollee is entitled only under that program.

(2) *Supplemental services elected by an enrollee.* (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

(3) *Supplemental services imposed by a risk HMO or CMP.* (i) Subject to CMS's approval, a risk HMO or CMP may require Medicare enrollees to accept and pay for services in addition to those covered by Medicare. (ii) If the HMO or CMP elects this option, it must impose the requirement on all Medicare enrollees, without regard to health status. (iii) CMS approves supplemental benefits of this type if CMS determines that imposition of the requirements will not discourage other Medicare beneficiaries from enrolling in the risk HMO or CMP.

(4) *Additional benefits from risk HMOs or CMPs required by statute.* Subject to

the conditions stated in §417.442, a new Medicare enrollee or a current nonrisk Medicare enrollee who converts to risk reimbursement under §417.444 is eligible to receive, in addition to the covered Part A and Part B benefits for which he or she is eligible, benefits consisting of one or both of the following:

(i) A reduction in the HMO's or CMP's premium rate or in other charges for services furnished to Medicare enrollees.

(ii) Provision of health benefits or services beyond the required Part A and Part B coverage.

(5) *Special supplemental benefits.* Under conditions described in §417.444(c), current nonrisk Medicare enrollees who are not converted to the risk portion of the contract, may enroll in a special supplemental plan, if offered by the HMO or CMP, for some or all of the additional benefits described in paragraph (b)(4) of this section.

(c) *Limitation on hospice care*—(1) *Extent of limitation*—(i) *Basic rule.* Except as provided in paragraph (c)(1)(ii) of this section, a Medicare enrollee who elects to receive hospice care under §418.24 of this chapter waives the right to receive from the HMO or CMP any Medicare services (including services equivalent to hospice care) that are related to the terminal condition for which the enrollee elected hospice care, or to a related condition.

(ii) *Exception.* An enrollee who elects hospice care retains the right to services furnished by his or her attending physician if that physician—

(A) Is an employee or contractor of the HMO or CMP; and

(B) Is not an employee of the designated hospice and does not receive compensation from the hospice for those services.

(2) *Effective date of limitation.* The limitation in paragraph (c)(1) of this section begins on the effective date of the beneficiary's election of hospice care and remains in effect until the earlier of the following:

(i) The effective date of the enrollee's revocation of the election of hospice care as described in §418.28 of this chapter.

(ii) The date the enrollee exhausts his or her hospice benefits.

(3) *Payment to HMO or CMP.* For the period that the Medicare enrollee's election of hospice care is in effect, CMS pays a cost HMO or CMP only as described in §417.585.

(d) *Limitation on provision of inpatient hospital services.* If a beneficiary's effective date of coverage, as specified in §417.450, in a risk HMO or CMP occurs during an inpatient stay in a hospital paid for under part 412 of this chapter, the HMO or CMP—

(1) Is not responsible for the provision of any of the inpatient hospital services under Part A during the stay and is not required to pay for those services;

(2) Must assume responsibility for payment for or provision of inpatient hospital services under Part A on the day after the day of discharge from the inpatient stay; and

(3) Is responsible for the full scope of services under paragraph (b) of this section, other than inpatient hospital services under Part A, beginning on the effective date of enrollment.

(e) *Extension of provision of inpatient hospital services.* If an enrollee's effective date of disenrollment, as defined by §417.460, occurs during an inpatient stay in a hospital paid for under part 412 of this chapter and the stay is provided or arranged for by the HMO or CMP, or the HMO or CMP is financially responsible for the hospitalization under paragraph (a)(2) of this section, the HMO or CMP—

(1) Is financially responsible for payment of the inpatient services under Part A through the date the beneficiary is discharged from the inpatient stay; and

(2) Is not responsible for the provision of services, furnished on or after the effective date of disenrollment, other than inpatient hospital services under Part A.

(f) *Notice of noncoverage of inpatient hospital care.* (1) If an enrollee is an inpatient of a hospital, entitlement to inpatient hospital care continues until he or she receives notice of noncoverage of that care.

(2) Before giving notice of noncoverage, the HMO or CMP must obtain the concurrence of its affiliated physician responsible for the hospital care of

the enrollee, or other physician as authorized by the HMO or CMP.

(3) The HMO or CMP must give the enrollee written notice that includes the following:

(i) The reason why inpatient hospital care is no longer needed.

(ii) The effective date of the enrollee's liability for continued inpatient care.

(iii) The enrollee's appeal rights.

(4) If the HMO or CMP delegates to the hospital the determination of noncoverage of inpatient care, the hospital obtains the concurrence of the HMO- or CMP-affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP, and sends notice, following the procedures set forth in § 412.42(c)(3) of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 70 FR 4525, Jan. 28, 2005]

§ 417.442 Risk HMO's and CMP's: Conditions for provision of additional benefits.

(a) *General rule.* Except as provided in paragraph (b) of this section, a risk HMO or CMP must, during any contract period, provide to its Medicare enrollees the additional benefits described in § 417.440(b)(4) if its ACRs (calculated in accordance with § 417.594) are less than the average per capita rates that CMS pays for the Medicare enrollees during the contract period.

(b) *Exceptions*—(1) *Reduced payment election.* An HMO or CMP is not obligated to furnish additional services under paragraph (a) of this section if it has requested a reduction in its monthly payment from CMS under § 417.592(e), and it—

(i) Elects to receive reduced payment so that there is no difference between the average of its per capita rates of payment and its ACR; or

(ii) Elects to receive partially reduced payment and furnish Medicare enrollees with additional benefits described in § 417.440 (b)(4) so that the combined value of benefits and reduced payment is equivalent to the difference between the average of its per capita rates of payment and its ACR.

(2) *Benefit stabilization fund.* An HMO or CMP may elect to have a part of the value of the additional benefits it must provide under paragraph (a) of this section withheld in a benefit stabilization fund as described in § 417.596.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.444 Special rules for certain enrollees of risk HMOs and CMPs.

(a) *Applicability.* This section applies to any Medicare enrollee of a risk HMO or CMP who meets the following conditions:

(1) On February 1, 1985, was enrolled—

(i) In an HMO or CMP that had in effect a cost contract entered into under section 1876 of the Act in accordance with regulations in effect before February 1, 1985; or

(ii) In an HCPP that was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act.

(2) Has continued enrollment in the same entity without interruption or disenrolled after February 1, 1985, and later reenrolled in the same entity.

(b) *Retention of nonrisk status*—(1) A ''nonrisk'' enrollee is a Medicare beneficiary who meets the conditions of paragraph (a) of this section and is enrolled in an entity that enters into a risk contract as an HMO or CMP. A ''nonrisk'' enrollee may retain nonrisk status indefinitely unless CMS determines under paragraph (c)(1) of this section, that the enrollee's status must be changed, or the enrollee requests the change, as provided in paragraph (c)(2) of this section.

(2) A nonrisk enrollee of a risk HMO or CMP is not entitled to additional benefits under § 417.442.

(c) *Conversion to risk status*—(1) *Conversion based on CMS determination.* If CMS determines that, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the HMO or CMP, all of its nonrisk Medicare enrollees must be covered under the risk provisions of the contract, the conversion process is as follows:

(i) CMS notifies each affected enrollee of the decision at least 90 days prior to the effective date.

(ii) The nonrisk Medicare enrollees complete and sign forms stating that they understand and accept the new rules and benefits that will be applicable to them.

(iii) The HMO or CMP notifies each affected enrollee, in writing, at least 30 days in advance, of the date upon which his or her coverage under the risk portion of the contract takes effect.

(2) *Conversion based on enrollee's request.* A nonrisk Medicare enrollee requests, using a form identical or similar to the form described in paragraph (c)(1) of this section, that he or she be covered under the risk portion of the contract.

(d) *Notification.* An HMO or CMP converting from a cost contract to a risk contract must, within 60 days of signing the risk contract, inform nonrisk enrollees of their right to remain nonrisk Medicare enrollees or to convert to risk enrollment at any time in accordance with paragraph (c)(2) of this section.

[58 FR 38073, July 15, 1993]

§417.446 [Reserved]

§417.448 Restriction on payments for services received by Medicare enrollees of risk HMOs or CMPs.

(a) *Basic rule.* Except for emergency and urgently needed services as defined in §417.401, risk HMOs or CMPs are not required to make payments to or on behalf of certain Medicare enrollees, for any services received by the enrollees that are not provided—

(1) Directly by the HMO or CMP; or

(2) Through arrangements made by the HMO or CMP.

(b) *Application.* The restriction on payments for services imposed by paragraph (a) of this section applies to services received by—

(1) New Medicare enrollees;

(2) Nonrisk Medicare enrollees who convert to risk reimbursement; and

(3) Nonrisk Medicare enrollees who elect special supplemental benefit plans.

(c) *End of restriction.* The restriction of payments imposed by paragraph (a) of this section ends when a Medicare enrollee leaves the HMO's or CMP's geographic area for an extended period as defined in §471.460(a)(2) and the HMO or CMP and the enrollee make arrangements for enrollment to continue as provided in §417.460(a)(2)(iv).

(d) *Timing.* The effective date for the end of the restriction on payments, as discussed in paragraph (c) of this section is the first day of the first month following the month in which the enrollee notifies the HMO or CMP as required in §417.436(a)(9), that he or she has left the HMO's or CMP's geographic area for an extended period.

[51 FR 28573, Aug. 8, 1986, as amended at 56 FR 46571, Sept. 13, 1991; 58 FR 38079, July 15, 1993]

§417.450 Effective date of coverage.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, and notwithstanding the provisions of §417.440(d).

(1) CMS's liability for payments to an HMO or CMP on behalf of a Medicare beneficiary begins on the first day of the month in which he or she is—

(i) Entitled to Medicare benefits; and

(ii) Enrolled in an HMO or CMP; and

(2) The effective month of coverage may not be earlier than the first month after, nor later than the third month after the month in which CMS receives the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in CMS records.

(b) *Exceptions.* (1) CMS may approve a later month if it is requested by the HMO or CMP and the beneficiary.

(2) If an individual becomes an HMO or CMP enrollee before becoming entitled to Medicare Part B benefits, the effective month of coverage is the first month for which he or she becomes entitled to Medicare Part B benefits.

(c) *Notice of effective date of coverage.* For each beneficiary added to CMS's records as an enrollee of an HMO or CMP, CMS gives the HMO or CMP prompt written notice of the month with which CMS's liability begins.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance.* (1) A Medicare enrollee of an HMO or CMP is

responsible for applicable Medicare deductible and coinsurance amounts, unless the HMO's or CMP's charges for these amounts are reduced under the additional benefits provision of § 417.442.

(2) The deductible and coinsurance amounts may be paid by or on behalf of the enrollee in the form of a premium, membership fee, charge per unit, or other similar charge.

(3) The sum of the amounts the HMO or CMP charges its Medicare enrollees for Medicare deductibles and coinsurance may not exceed, on the average, the actuarial value of the deductible and coinsurance the Medicare enrollees otherwise would have been liable for had they not enrolled in the HMO or CMP or in another HMO or CMP.

(b) *Services not covered under Medicare.* Unless the services are provided as additional benefits under § 417.442, a Medicare enrollee of an HMO or CMP is liable for payment for—

(1) All services that are not covered under Medicare Part A or Part B; or

(2) If entitled only to Medicare Part B benefits, all services that are not covered under Medicare Part B.

(c) *Services for which Medicare is not primary payer.* A Medicare enrollee of an HMO or CMP is liable for payments made to the enrollee for all covered services for which Medicare is not the primary payer as provided in § 417.528.

(d) *Optional supplemental benefits plan.* (1) The HMO or CMP may offer its Medicare enrollees a supplemental benefit plan to cover deductible and coinsurance amounts, or services not covered under Medicare, or both.

(2) If a supplemental benefit plan premium includes charges for both noncovered services and the deductible and coinsurance amounts applicable to covered services, the portion of the premium that is for deductibles and coinsurance must be computed separately and must be disclosed to the beneficiary during the enrollment process and before he or she elects coverage options.

(3) The sum of the amounts an HMO or CMP charges its Medicare enrollees for services that are not covered under Part A or Part B may not exceed the ACR for these services.

(e) *Coverage of Part A services for Part B-only Medicare enrollees.* If an HMO or CMP furnishes coverage of Medicare Part A services to a Medicare enrollee entitled to Part B only, the HMO's or CMP's premium (or other payment method) for these services may not exceed the ACR for these services. In addition, if a risk HMO or CMP furnishes these services and supplemental services, which are the same as the additional benefits furnished Medicare enrollees of the HMO or CMP who are entitled to benefits under both Parts A and B, the HMO's or CMP's combined premium for both these groups of services that the Part B enrollee must pay may not exceed 95 percent of the weighted average AAPCC for Part A services (or the Medicare payment for Part A services, if it is less) for the Medicare enrollee of the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.454 Charges to Medicare enrollees.

(a) *Limits on charges.* The HMO or CMP must agree to charge its Medicare enrollees only for the—

(1) Deductible and coinsurance amounts applicable to furnished covered services;

(2) Charges for noncovered services or services for which the enrollee is liable as described in § 417.452; and

(3) Services for which Medicare is not the primary payor as provided in § 417.528.

(b) *Limit on charges for inpatient hospital care.* If a Medicare enrollee who is an inpatient of a hospital requests immediate QIO review (as provided in § 417.605) of any determination by the hospital furnishing services or the HMO or CMP that the inpatient hospital services will no longer be covered, the HMO or CMP may not charge the enrollee for any inpatient care costs incured before noon of the first working day after the QIO issues its review decision.

(c) *Reporting requirements.* A risk HMO or CMP must report, within 90 days after the end of the contract period, all premiums, enrollment fees, and other charges collected from its Medicare enrollees during that period.

(d) *Limit on charges for specified preventive services.* An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in §410.152(l)).

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which HMOs' cost sharing may not exceed that required under original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 76 FR 21561, Apr. 15, 2011]

§417.456 Refunds to Medicare enrollees.

(a) *Definitions.* As used in this section—

Amounts incorrectly collected means amounts collected that are in excess of those specified in §417.452. It includes amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined to have been entitled to Medicare benefits and CMS is liable for payments as specified in §417.450.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the HMO or CMP if they were—

(1) Emergency services;

(2) Urgently needed services for which the HMO or CMP has assumed financial responsibility; or

(3) On appeal under subpart Q of this part, found to be services the enrollee was entitled to have furnished by the HMO or CMP.

(b) *Basic commitment.* An HMO or CMP must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and any other amounts due the enrollees or others on their behalf.

(c) *Refund by lump sum payment.* An HMO or CMP must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

(1) Incorrectly collected amounts that were not collected as premiums.

(2) Other amounts due.

(3) All amounts due, if the HMO or CMP is going out of business.

(d) *Refund by premium adjustment or lump sum payment or both.* An HMO or CMP may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for amounts that were incorrectly collected in the form of premiums or through a combination of premium payments and other charges.

(e) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort by the HMO or CMP, the HMO or CMP must make the refund in accordance with State law.

(f) *Reduction by CMS.* If the HMO or CMP does not make refund in accordance with paragraphs (b) through (d) of this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces its payment to the HMO or CMP by the amounts incorrectly collected or otherwise due, and arranges for those amounts to be paid to the Medicare enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.458 Recoupment of uncollected deductible and coinsurance amounts.

An HMO or CMP agrees not to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period except in the following circumstances:

(a) The HMO or CMP failed to collect the deductible and coinsurance

amounts during the contract period in which they were due because of—

(1) Underestimation of the actuarial value of the deductible and coinsurance amounts; or

(2) A billing error.

(b) The HMO or CMP has identified the amounts and obtained advance CMS approval of the recoupment and the method and timing of recoupment.

(c) The HMO or CMP collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

(a) *General rule.* Except as provided in paragraphs (b) through (i) of this section, an HMO or CMP may not—

(1) Disenroll a Medicare beneficiary; or

(2) Orally or in writing, or by any action or inaction, request or encourage a Medicare enrollee to disenroll.

(b) *Bases for disenrollment: Overview*—(1) *Optional disenrollment.* Generally, an HMO or CMP may disenroll a Medicare enrollee if he or she—

(i) Fails to pay the required premiums or other charges;

(ii) Commits fraud or permits abuse of his or her enrollment card; or

(iii) Behaves in a manner that seriously impairs the HMO's or CMP's ability to furnish health care services to the particular enrollee or to other enrollees.

(2) *Required disenrollment.* Generally, an HMO or CMP must disenroll a Medicare enrollee if he or she—

(i) Moves out of the HMO's or CMP's geographic area;

(ii) Fails to convert to the risk provisions of the HMO's or CMP's Medicare contract;

(iii) Loses entitlement to Medicare Part B benefits; or

(iv) Dies.

(3) *Related provisions.* Specific requirements, limitations, and exceptions are set forth in paragraphs (c) through (i) of this section.

(c) *Failure to pay premiums or other charges*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, an HMO or CMP may disenroll a Medicare enrollee who fails to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, if the HMO or CMP—

(i) Can demonstrate to CMS that it made reasonable efforts to collect the unpaid amount;

(ii) Gives the enrollee written notice of disenrollment, including an explanation of the enrollee's right to a hearing under the HMO's or CMP's grievance procedures; and

(iii) Sends the notice of disenrollment to the enrollee before it notifies CMS.

(2) *Exception.* If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and other charges, the HMO or CMP may discontinue the optional benefits but may not disenroll the beneficiary.

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(d) *Enrollee commits fraud or permits abuse of the enrollment card*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare beneficiary if the beneficiary—

(i) Knowingly provides, on the application form, fraudulent information

that materially affects the beneficiary's eligibility to enroll in the HMO or CMP; or

(ii) Intentionally permits others to use his or her enrollment card to obtain services from the HMO or CMP.

(2) *Notice requirement.* If disenrollment is for either of the reasons specified in paragraph (d)(1) of this section, the HMO or CMP must give the beneficiary a written notice of termination of enrollment.

(i) The notice must be mailed to the enrollee before submission of the disenrollment notice to CMS.

(ii) The notice must include an explanation of the enrollee's right to have the disenrollment heard under the grievance procedures established in accordance with §417.436.

(3) *Report to the Inspector General.* The HMO or CMP must report to the Office of the Inspector General of the Department any disenrollment based on fraud or abuse by the enrollee.

(e) *Disenrollment for cause*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare enrollee for cause if the enrollee's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continuing enrollment in the HMO or CMP seriously impairs the HMO's or CMP's ability to furnish services to either the particular enrollee or other enrollees.

(2) *Effort to resolve the problem.* The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures.

(3) *Consideration of extenuating circumstances.* The HMO or CMP must ascertain that the enrollee's behavior is not related to the use of medical services or to mental illness.

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (e)(3) of this section.

(5) *CMS review of an HMO's or CMP's proposed disenrollment for cause.* (i) CMS decides on the basis of review of the documentation submitted by the HMO or CMP, whether disenrollment requirements have been met.

(ii) CMS makes this decision within 20 working days after receipt of the documentation material, and notifies the HMO or CMP within 5 working days after making its decision.

(6) *Effective date of disenrollment.* If CMS permits an HMO or CMP to disenroll an enrollee for cause, the disenrollment takes effect on the first day of the calendar month after the month in which the HMO or CMP gives the enrollee a written notice of disenrollment that meets the requirements set forth in paragraphs (d)(2)(i) and (d)(2)(ii) of this section.

(f) *Enrollee moves out of the HMO's or CMP's geographic area*—(1) *Basic rules*—(i) *Disenrollment.* Except as provided in paragraph (f)(2) of this section, an HMO or CMP must disenroll a Medicare enrollee who moves out of its geographic area if the HMO or CMP establishes, on the basis of a written statement from the enrollee, or other evidence acceptable to CMS, that the enrollee has permanently moved out of its geographic area.

(ii) *Notice requirement.* The HMO or CMP must comply with the notice requirements set forth in paragraph (d)(2) of this section.

(iii) *Effect on geographic area.* Failure to disenroll an enrollee who has moved out of the HMO's or CMP's geographic area does not expand that area to encompass the location of the enrollee's new residence.

(2) *Exception.* An HMO or CMP may retain a Medicare enrollee who is absent from its geographic area for an extended period, but who remains within the United States as defined in §400.200 of this chapter if the enrollee agrees. For purposes of this exception, the following provisions apply:

(i) An absence for an extended period means an uninterrupted absence from the HMO's or CMP's geographic area for more than 90 days but less than 1 year.

(ii) The HMO or CMP and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee is absent for an extended period from the HMO's or CMP's geographic area. However, restrictions may not be imposed on the scope of services described in §417.440.

(iii) HMOs and CMPs that choose to exercise this exception must make the

option available to all Medicare enrollees who are absent for an extended period from their geographic areas. However, HMOs and CMPs may limit this option to enrollees who go to a geographic area served by an affiliated HMO or CMP.

(iv) As used in this paragraph, ''affiliated HMO or CMP'' means an HMO or CMP that—

(A) Is under common ownership or control of the HMO or CMP that seeks to retain the absent enrollees; or

(B) Has in effect an agreement to furnish services to enrollees who are on an extended absence from the geographic area of the HMO or CMP that seeks to retain them.

(v) When the enrollee returns to the HMO's or CMP's geographic area (even temporarily), the restrictions of §417.448(a) (which limit payment for services not provided or arranged for by the HMO or CMP) apply again immediately.

(vi) If the enrollee fails to return to the HMO's or CMP's geographic area within 1 year from the date he or she left that area, the HMO or CMP must disenroll the beneficiary on the first day of the month following the anniversary of the date the enrollee left that area in accordance with paragraph (f)(1) of this section.

(g) *Failure to convert to risk provisions of Medicare contract*—(1) *Basis for disenrollment.* A risk HMO or CMP must disenroll a nonrisk Medicare enrollee who refuses to convert to the risk provisions of the Medicare contract after CMS determines that all of the HMO's or CMP's nonrisk Medicare enrollees must convert.

(2) *Advance notice requirement.* At least 30 days before it gives CMS notice of disenrollment, the HMO or CMP must give the enrollee written notice of the fact that failure to convert will result in disenrollment.

(h) *Loss of entitlement to Medicare benefits*—(1) *Loss of entitlement to Part A benefits.* If an enrollee loses entitlement to benefits under Part A of Medicare but remains entitled to benefits under Part B, the enrollee automatically continues as a Medicare enrollee of the HMO or CMP and is entitled to receive and have payment made for Part B services, beginning with the month immediately following the last month of his or her entitlement to Part A benefits.

(2) *Loss of entitlement to Part B benefits.* If a Medicare enrollee loses entitlement to Part B benefits, the HMO or CMP must disenroll him or her as a Medicare enrollee effective with the month following the last month of entitlement to Part B benefits. However, the HMO or CMP may continue to enroll the individual under its regular plan if the individual so chooses.

(i) *Death of the enrollee.* Disenrollment is effective with the month following the month of death.

[60 FR 45678, Sept. 1, 1995, as amended at 77 FR 22166, Apr. 12, 2012]

§ 417.461 Disenrollment by the enrollee.

(a) *Request for disenrollment.* (1) A Medicare enrollee who wishes to disenroll may at any time give the HMO or CMP a signed, dated request in the form and manner prescribed by CMS.

(2) The enrollee may request a certain disenrollment date but it may be no earlier than the first day of the month following the month in which the HMO or CMP receives the request.

(b) *Responsibilities of the HMO or CMP.* The HMO or CMP must—

(1) Submit a disenrollment notice to CMS promptly;

(2) Provide the enrollee with a copy of the request for disenrollment; and

(3) In the case of a risk HMO or CMP, also provide the enrollee with a statement explaining that he or she—

(i) Remains enrolled until the effective date of disenrollment; and

(ii) Until that date, is subject to the restrictions of §417.448(a) under which neither the HMO or CMP nor CMS pays for services not provided or arranged for by the HMO or CMP.

(c) *Effect of failure to submit disenrollment notice to CMS promptly.* If the HMO or CMP fails to submit timely the correct and complete notice required in paragraph (b)(1) of this section, the HMO or CMP must reimburse CMS for any capitation payments received after the month in which payments would have ceased if the requirement had been met timely.

[60 FR 45679, Sept. 1, 1995]

§417.464 End of CMS's liability for payment: Disenrollment of beneficiaries and termination or default of contract.

(a) *Effect of disenrollment: General rule.* (1) CMS's liability for monthly capitation payments to the HMO or CMP generally ends as of the first day of the month following the month in which disenrollment is effective, as shown on CMS's records.

(2) Disenrollment is effective no earlier than the month immediately after, and no later than the third month after, the month in which CMS receives the disenrollment notice in acceptable form.

(b) *Effect of disenrollment: Special rules*—(1) *Fraud or abuse by the enrollee.* If disenrollment is on the basis of fraud committed or abuse permitted by the enrollee, CMS's liability ends as of the first day of the month in which disenrollment is effective.

(2) *Loss of entitlement to Part B benefits.* If disenrollment is on the basis of loss of entitlement to Part B benefits, CMS's liability ends as of the first day of the month following the last month of Part B entitlement.

(3) *Death of enrollee.* If the enrollee dies, CMS's liability ends as of the first day of the month following the month of death.

(4) *Disenrollment at enrollee's request.* If disenrollment is in response to the enrollee's request, CMS's liability ends as of the first day of the month following the month of termination requested by the enrollee.

(c) *Effect of termination or default of contract*—(1) *Termination of contract.* If the contract between CMS and the HMO or CMP is terminated by mutual consent or by unilateral action of either party, CMS's liability for payments ends as of the first day of the month after the last month for which the contract is in effect.

(2) *Default of contract.* If the HMO or CMP defaults on the contract before the end of the contract year because of bankruptcy or other reasons, CMS—

(i) Determines the month in which its liability for payments ends; and

(ii) Notifies the HMO or CMP and all affected Medicare enrollees as soon as practicable.

[60 FR 45680, Sept. 1, 1995]

Subpart L—Medicare Contract Requirements

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.470 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1857(e)(2) of the Act pertaining to cost sharing in enrollment-related costs and section 1876(c), (g), (h), and (i) of the Act that pertain to the contract between CMS and an HMO or CMP for participation in the Medicare program.

(b) *Scope.* This subpart sets forth—

(1) Specific contract requirements; and

(2) Procedures for renewal, nonrenewal, or termination of a contract.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 62 FR 63673, Dec. 2, 1997]

§417.472 Basic contract requirements.

(a) *Submittal of contract.* An HMO or CMP that wishes to contract with CMS to furnish services to Medicare beneficiaries must submit a signed contract that meets the requirements of this subpart and any other requirements established by CMS.

(b) *Agreement to comply with regulations and instructions.* The contract must provide that the HMO or CMP agrees to comply with all the applicable requirements and conditions set forth in this subpart and in general instructions issued by CMS.

(c) *Other contract provisions.* In addition to the requirements set forth in §§417.474 through 417.488, the contract must contain any other terms and conditions that CMS requires to implement section 1876 of the Act.

(d) *Exemption from Federal procurement regulations.* The Federal Acquisition Regulations and HHS Acquisition Regulations contained in title 48 of the Code of Federal Regulations do not apply to Medicare contracts under section 1876 of the Act.

(e) *Compliance with civil rights laws.* The HMO or CMP must comply with title VI of the Civil Rights Act of 1964 (regulations at 45 CFR part 80), section 504 of the Rehabilitation Act of 1973 (regulations at 45 CFR part 84), and the

Age Discrimination Act of 1975 (regulations at 45 CFR part 91).

(f) *Requirements for advance directives.* The HMO or CMP must meet all the requirements for advance directives at § 417.436(d).

(g) *Authority to waive conflicting contract requirements.* Under section 1876(i)(5) of the Act, CMS is authorized to administer the terms of this subpart without regard to provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if it determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(h) *Collection of fees from risk HMOs and CMPs.* (1) The rules set forth in § 422.10 of this chapter for M+C plans also apply to collection of fees from risk HMOs and CMPs.

(2) In applying the part 422 rules, references to ''M+C organizations'' or ''M+C plans'' must be read as references to ''risk HMOs and CMPs''.

(i) The HMO or CMP must comply with the requirements at § 422.152(b)(5).

(j) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38079, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 63 FR 35067, June 26, 1998; 75 FR 19802, Apr. 15, 2010]

§ 417.474 Effective date and term of contract.

(a) *Effective date.* The contract must specify its effective date, which may not be earlier than the date it is signed by both CMS and the HMO or CMP.

(b) *Term.* The contract must specify the duration of its term as follows:

(1) For the initial term, at least 12 months, but no more than 23 months.

(2) For any subsequent term, 12 months.

[60 FR 45680, Sept. 1, 1995]

§ 417.476 Waived conditions.

If CMS waives any of the qualifying conditions required under subpart J of this part, the contract must specify the following information for each waived condition:

(a) The specific terms of the waiver.

(b) The expiration date of the waiver.

(c) Any other information required by CMS.

[60 FR 45680, Sept. 1, 1995]

§ 417.478 Requirements of other laws and regulations.

The contract must provide that the HMO or CMP agrees to comply with—

(a) The requirements for QIO review of services furnished to Medicare enrollees as set forth in subchapter D of this chapter;

(b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;

(c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect enrollees of the HMO or CMP; and

(d) The reporting requirements in § 417.126(a), which pertain to the monitoring of an HMO's or CMP's continued compliance.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, 38082, July 15, 1993]

§ 417.479 Requirements for physician incentive plans.

(a) The contract must specify that an HMO or CMP may operate a physician incentive plan only if—

(1) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual enrollee; and

(2) The stop-loss protection, enrollee survey, and disclosure requirements of this section are met.

(b) *Applicability.* The requirements in this section apply to physician incentive plans between HMOs and CMP and

individual physicians or physician groups with which they contract to provide medical services to enrollees. The requirements in this section also apply to subcontracting arrangements as specified in §417.479(i). These requirements apply only to physician incentive plans that base compensation (in whole or in part) on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries.

(c) *Definitions.* For purposes of this section:

Bonus means a payment an HMO or CMP makes to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) that an organization pays a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Payments means any amounts the HMO or CMP pays physicians or physician groups for services they furnish directly, plus amounts paid for administration and amounts paid (in whole or in part) based on use and costs of referral services (such as withhold amounts, bonuses based on referral levels, and any other compensation to the physician or physician group to influence the use of referral services). Bonuses and other compensation that are not based on referral levels (such as bonuses based solely on quality of care furnished, patient satisfaction, and participation on committees) are not considered payments for purposes of this section.

Physician group means a partnership, association, corporation, individual practice association, or other group that distributes income from the practice among members. An individual practice association is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement between an HMO or CMP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Medicare beneficiaries or Medicaid beneficiaries enrolled in the HMO or CMP.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk.

Withhold means a percentage of payments or set dollar amounts that an HMO or CMP deducts from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(d) *Prohibited physician payments.* No specific payment of any kind may be made directly or indirectly under the incentive plan to a physician or physician group as an inducement to reduce or limit covered medically necessary services covered under the HMO's or CMP's contract furnished to an individual enrollee. Indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(e) *General rule: Determination of substantial financial risk.* Substantial financial risk occurs when the incentive arrangements place the physician or physician group at risk for amounts beyond the risk threshold, if the risk is based on the use or costs of referral services. Amounts at risk based solely on factors other than a physician's or physician group's referral levels do not contribute to the determination of substantial financial risk. The risk threshold is 25 percent.

(f) *Arrangements that cause substantial financial risk.* For purposes of this paragraph, *potential payments* means the maximum anticipated total payments (based on the most recent year's utilization and experience and any current or anticipated factors that may affect payment amounts) that could be received if use or costs of referral services were low enough. The following physician incentive plans cause substantial financial risk if risk is based

(in whole or in part) on use or costs of referral services and the patient panel size is not greater than 25,000 patients:

(1) Withholds greater than 25 percent of potential payments.

(2) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(3) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(4) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—

Withhold = 0.75 (Bonus %) + 25%.

(5) Capitation, arrangements, if—

(i) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments; or

(ii) The maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract.

(6) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(g) *Requirements for physician incentive plans that place physicians at substantial financial risk.* HMOs and CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk must do the following:

(1) Conduct enrollee surveys. These surveys must—

(i) Include either all current Medicare/Medicaid enrollees in the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees;

(ii) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(iii) Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services; and

(iv) Be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

(2) Ensure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(i) If aggregate stop-loss protection is provided, it must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(2) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

Panel size	Single combined limit	Separate institutional limit	Separate professional limit
1–1000	$6,000	$10,000	$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	none	none	none

(h) *Disclosure and other requirements for organizations with physician incentive plans*—(1) *Disclosure to CMS.* Each health maintenance organization or competitive medical plan must provide

to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—

(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

(ii) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled;

(iii) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled;

(iv) The distribution of payments to physicians from the risk pool is not calculated separately by patient category; and

(v) The terms of the risk borne by the physicians or physician group are comparable for all categories of patients being pooled.

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

(i) Whether the prepaid plan uses a physician incentive plan that affects the use of referral services.

(ii) The type of incentive arrangement.

(iii) Whether stop-loss protection is provided.

(iv) If the prepaid plan was required to conduct a survey, a summary of the survey results.

(i) *Requirements related to subcontracting arrangements*—(1) *Physician groups.* An HMO or CMP that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish must do the following:

(i) Disclose to CMS any incentive plan between the physician group and its individual physicians that bases compensation to the physician on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information specified in paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) Provide adequate stop-loss protection to the individual physicians.

(iii) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(2) *Intermediate entities.* An HMO or CMP that contracts with an entity (other than a physician group) for the provision of services to Medicare beneficiaries must do the following:

(i) Disclose to CMS any incentive plan between the entity and a physician or physician group that bases compensation to the physician or physician group on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information required to be disclosed under paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) If the physician incentive plan puts a physician or physician group at substantial financial risk for the cost of services the physician or physician group does not furnish—

(A) Meet the stop-loss protection requirements of this subpart; and

(B) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(3) For purposes of paragraph (i)(2) of this section, an entity includes, but is not limited to, an individual practice association that contracts with one or more physician groups and a physician hospital organization.

(j) *Sanctions against the HMO or CMP.* CMS may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at §417.500, if CMS determines that an HMO or CMP fails to comply with the requirements of this section.

[61 FR 13446, Mar. 27, 1996; 61 FR 46385, Sept. 3, 1996, as amended at 61 FR 69049, Dec. 31, 1996; 68 FR 50855, Aug. 22, 2003]

§417.480 Maintenance of records: Cost HMOs and CMPs.

A reasonable cost contract must provide that the HMO or CMP agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, HMO or CMP, and operation of the HMO's or CMP's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

(4) Asset acquisition, lease, sale, or other action.

(5) Agreements, contracts, and subcontracts.

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the HMO's or CMP's fee-for-service patients.

(8) Matters pertaining to costs of operations.

(9) Amounts of income received by source and payment.

(10) Cash flow statements.

(11) Any financial reports filed with other Federal programs or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.481 Maintenance of records: Risk HMOs and CMPs.

A risk contract must provide that the HMO or CMP agrees to maintain and make available to CMS upon request, books, records, documents, and other evidence of acounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.482 Access to facilities and records.

The contract must provide that the HMO or CMP agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the HMO or CMP when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or CMP or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract.

(d) HHS may evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three prior periods, when there is reasonable evidence of some need for that inspection.

(e) In the case of a reasonable cost HMO or CMP to make available for the purposes specified in paragraphs (a), (b), (c), and (d) of this section, its premises, physical facilities, and equipment, its records relating to its Medicare enrollees, the records specified in § 417.480 and any additional relevant information that CMS may require.

(f) That the right to inspect, evaluate, and audit, will extend through three years from the date of the final settlement for any contract period unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the HMO or CMP at least 30 days before the normal disposition date;

(2) There has been a termination, dispute, fraud, or similar fault by the HMO or CMP, in which case the retention may be extended to three years from the date of any resulting final settlement; or

(3) CMS determines that there is a reasonable possibility of fraud, in

which case it may reopen a final settlement at any time.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.484 Requirement applicable to related entities.

(a) *Definition.* As used in this section, *related entity* means any entity that is related to the HMO or CMP by common ownership or control and—

(1) Performs some of the HMO's or CMP's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the HMO or CMP at a cost of more than $2,500 during a contract period.

(b) *Requirement.* The contract must provide that the HMO or CMP agrees to require all related entities to agree that—

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) The right under paragraph (b)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in § 417.482(f).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.486 Disclosure of information and confidentiality.

The contract must provide that the HMO or CMP agrees to the following:

(a) To submit to CMS—

(1) All financial information required under subpart O of this part and for final settlement; and

(2) Any other information necessary for the administration or evaluation of the Medicare program.

(b) To comply with the requirements set forth in part 420, subpart C, of this chapter pertaining to the disclosure of ownership and control information.

(c) To comply with the requirements of the Privacy Act, as implemented by 45 CFR part 5b and subpart B of part 401 of this chapter, with respect to any system of records developed in performing carrier or intermediary functions under §§ 417.532 and 417.533.

(d) To meet the confidentiality requirements of § 482.24(b)(3) of this chapter for medical records and for all other enrollee information that is—

(1) Contained in its records or obtained from CMS or other sources; and

(2) Not covered under paragraph (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.488 Notice of termination and of available alternatives: Risk contract.

A risk contract must provide that the HMO or CMP agrees to give notice as follows if the contract is terminated:

(a) At least 60 days before the effective date of termination, to give its Medicare enrollees a written notice that—

(1) Specifies the termination date; and

(2) Describes the alternatives available for obtaining Medicare services after termination.

(b) To pay the cost of the written notices.

[60 FR 45680, Sept. 1, 1995]

§ 417.490 Renewal of contract.

A contract with an HMO or CMP is renewed automatically for the next 12-month period unless CMS or the HMO or CMP decides not to renew, in accordance with § 417.492.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.492 Nonrenewal of contract.

(a) *Nonrenewal by the HMO or CMP.* (1) If an HMO or CMP does not intend to renew its contract, it must—

(i) Give written notice to CMS at least 90 days before the end of the current contract period; and

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period.

(2) CMS may accept a nonrenewal notice submitted less than 90 days before the end of a contract period if—

(i) The HMO or CMP notifies its Medicare enrollees and the public in accordance with paragraph (a)(1) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program.

(b) *Nonrenewal by CMS*—(1) *Notice of nonrenewal.* If CMS decides not to renew a contract, it gives written notice of nonrenewal as follows:

(i) To the HMO or CMP at least 90 days before the end of the contract period.

(ii) To the HMO's or CMP's Medicare enrollees at least 60 days before the end of the contract period.

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in § 417.494(b).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010; 77 FR 22166, Apr. 12, 2012]

§ 417.494 Modification or termination of contract.

(a) *Modification or termination by mutual consent.* (1) CMS and an HMO or CMP may modify or terminate a contract at any time by written mutual consent.

(2) If the contract is modified, the HMO or CMP must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification.

(3) If the contract is terminated, the HMO or CMP must notify its Medicare enrollees, and CMS notifies the general public, at least 30 days before the termination date.

(b) *Termination by CMS.* (1) CMS may terminate a contract for any of the following reasons:

(i) The HMO or CMP has failed substantially to carry out the terms of the contract.

(ii) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the effective and efficient implementation of section 1876 of the Act.

(iii) The HMO or CMP has failed substantially to comply with the composition of enrollment requirements specified in § 417.413(d).

(iv) CMS determines that the HMO or CMP no longer meets the requirements of section 1876 of the Act and this subpart for being an HMO or CMP.

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

(3) An HMO or CMP with a risk contract must notify its Medicare enrollees of the termination as described in § 417.488.

(4) CMS notifies the HMO's or CMP's Medicare enrollees and the general public of the termination at least 30 days before the effective date of termination.

(c) *Termination by the HMO or CMP.* The HMO or CMP may terminate the contract if CMS has failed substantially to carry out the terms of the contract.

(1) The HMO or CMP must notify CMS at least 90 days before the effective date of the termination and must include in its notice the reasons for the termination.

(2) The HMO or CMP must notify its Medicare enrollees of the termination at least 60 days before the termination date. Risk HMOs or CMPs must also provide a written description of alternatives available for obtaining Medicare services after termination of the contract. The HMO or CMP is responsible for the cost of these notices.

(3) The HMO or CMP must notify the general public of the termination at least 30 days before the termination date.

(4) The contract is terminated effective 60 days after the HMO or CMP mails the notice to Medicare enrollees as required in paragraph (c)(2) of this section.

(5) CMS's liability for payment ends as of the first day of the month after the last month for which the contract is in effect.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 22322, June 11, 1987; 56 FR 46571, Sept. 13, 1991; 58 FR 38079, 38082, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010]

§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422 of this chapter.

[75 FR 19803, Apr. 15, 2010]

Subpart M—Change of Ownership and Leasing of Facilities: Effect on Medicare Contract

§ 417.520 Effect on HMO and CMP contracts.

(a) The provisions set forth in subpart L of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying these provisions, references to ''M+C organizations'' must be read as references to ''HMOs and CMPs''.

(c) In § 422.550, reference to ''subpart K of this part'' must be read as reference to ''subpart L of part 417 of this chapter''.

(d) In § 422.553, reference to ''subpart K of this part'' must be read as reference to ''subpart J of part 417 of this chapter''.

[63 FR 35067, June 26, 1998]

Subpart N—Medicare Payment to HMOs and CMPs: General Rules

§ 417.524 Payment to HMOs or CMPs: General.

(a) *Basic rule.* The payments that CMS makes to an HMO or CMP under this subpart and subparts O and P of this part for furnishing covered Medicare services are in place of any payment that CMS would otherwise make to a beneficiary or the HMO or CMP under sections 1814(b) and 1833(a) of the Act.

(b) *Basis of payment.* (1) CMS pays the HMOs or CMPs on either a reasonable cost basis or a risk basis depending on the type of contract the HMO or CMP has with CMS.

(2) In certain cases a risk HMO or CMP also receives payments on a reasonable cost basis for certain Medicare enrollees who retain nonrisk status, as provided in § 417.444, after the HMO or CMP enters into a risk contract.

[60 FR 46229, Sept. 6, 1995]

§ 417.526 Payment for covered services.

Subpart O of this part set forth the principles that CMS follows in determining Medicare payment to an HMO or CMP that has a reasonable cost contract. Subpart P of this part describes the per capita method of Medicare payment to HMOs or CMPs that contract on a risk basis.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

§ 417.528 Payment when Medicare is not primary payer.

(a) *Limits on payments and charges.* (1) CMS may not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(2) The circumstances under which an HMO or CMP may charge, or authorize a provider to charge, for covered Medicare services for which Medicare is not the primary payer are stated in paragraphs (b) and (c) of this section.

(b) *Charge to other insurers or the enrollee.* If a Medicare enrollee receives from an HMO or CMP covered services that are also covered under State or Federal worker's compensation, automobile medical, or any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the HMO or CMP may charge, or authorize a provider that furnished the service to charge—

(1) The insurance carrier, employer, or other entity that is liable to pay for these services; or

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or other entity.

(c) *Charge to group health plans (GHPs) or large group health plans (LGHPs).* An HMO or CMP may charge a GHP or LGHP for covered services it furnished to a Medicare enrollee and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP for these covered services if—

(1) The Medicare enrollee is covered under the plan; and

(2) Under section 1862(b) of the Act, CMS is precluded from paying for the covered services .

(d) *Responsibilities of HMO or CMP.* An HMO or CMP must—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act;

(2) Determine the amounts payable by these payers; and

(3) Coordinate the benefits of its Medicare enrollees with these payers.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

Subpart O—Medicare Payment: Cost Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.530 Basis and scope.

This subpart sets forth the principles that CMS follows to determine the amount it pays for services furnished by a cost HMO or CMP to its Medicare enrollees. These principles are based on sections 1861(v) and 1876 of the Act and are, for the most part, the same as those set forth—

(a) In part 412 of this chapter, for paying the costs of inpatient hospital services which, for cost HMOs and CMPs, are considered ''reasonable'' only if they do not exceed the amounts allowed under the prospective payment system; and

(b) In part 413 of this chapter, for the costs of all other covered services.

[60 FR 46230, Sept. 6, 1995]

§ 417.531 Hospice care services.

(a) If a Medicare enrollee of an HMO or CMP with a reasonable cost contract makes an election under § 418.24 of this chapter to receive hospice care services, payment for these services is made to the hospice that furnishes the services in accordance with part 418 of this chapter.

(b) While the enrollee's hospice election is in effect, CMS pays the HMO or CMP on a reasonable cost basis for only the following covered Medicare services furnished to the Medicare enrollee:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.532 General considerations.

(a) *Conditions and criteria for payment.* (1) The costs incurred by the HMO or CMP to furnish services covered by Medicare are reimbursable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients.

(2) In determining fair and equitable payment for the HMOs or CMPs, CMS generally applies the cost payment principles set forth in § 413.5 of this chapter.

(3) In judging whether costs are reasonable, CMS applies the weighted average of the AAPCCs of each class of the HMO's or CMP's Medicare enrollees (as defined in § 417.582) for the HMO's or CMP's geographic area as an absolute limitation on the total amount payable.

(b) *Method and amount of payment to the HMO or CMP.* (1) CMS makes interim per capita payments each month for each Medicare enrollee, equivalent

to the interim per capita cost rate determined in accordance with § 417.570.

(2) CMS adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the HMO or CMP, CMS deducts from the reasonable cost actually incurred by the HMO or CMP for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare Part A and Part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in the HMO or CMP or another HMO or CMP.

(c) *Election by HMO or CMP.* An HMO or CMP must elect, on an individual provider basis, one of the following methods for payment for hospital and SNF services it furnishes to Medicare enrollees:

(1) Direct payment by CMS.

(2) Direct payment by the HMO or CMP.

(d) *Notice of election.* The election must be made in writing before the beginning of the contract period and is binding for that period.

(e) *Payment by HMO or CMP.* If the HMO or CMP elects to pay providers directly, as provided in paragraph (c) of this section, it must—

(1) Determine the eligibility of its Medicare enrollees to receive covered services through the HMO or CMP;

(2) Make proper coverage decisions and appropriate payments, in accordance with §§ 421.100 and 421.200 of this chapter, for the services furnished to its Medicare enrollees;

(3) Ensure that providers maintain and furnish appropriate documentation of physician certification and recertification, to the extent required under subpart B of part 424 of this chapter; and

(4) Carry out any other procedures required by CMS.

(f) *Review of HMO's or CMP's bill processing capabilities.* If the HMO or CMP elects to pay providers directly, CMS determines whether the HMO or CMP has the experience and capability to carry out the responsibilities specified in paragraph (e) of this section in an efficient and effective manner.

(g) *Direct payment by CMS.* (1) If the HMO or CMP elects to have CMS pay for provider services, CMS pays each provider on a reasonable cost basis or under the PPS system, whichever is appropriate for the particular provider under part 412 or part 413 of this chapter.

(2) In computing the Medicare payment to the HMO or CMP, CMS deducts these payments and any other payments made by the Medicare intermediary or carrier on behalf of the HMO or CMP (such as payment for emergency or urgently needed services under § 417.558).

(h) *Payment for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP.* CMS pays the HMO or CMP for services it furnishes to Medicare beneficiaries who are not its enrollees through the HMO's or CMP's Medicare intermediary or carrier, as appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.533 Part B carrier responsibilities.

In paying for Part B services furnished to its enrollees by suppliers, the HMO or CMP must—

(a) Determine the eligibility of individuals to receive those services through the HMO or CMP;

(b) Make proper coverage decisions and appropriate payment as authorized under § 421.200 of this chapter for the services for which its Medicare enrollees are eligible; and

(c) Carry out any other procedures that CMS may require.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.534 Allowable costs.

(a) *Definition—Allowable costs* means the direct and indirect costs, including normal standby costs incurred by the HMO or CMP, that are proper and necessary for efficient delivery of needed health care services. They include the costs of furnishing services to the HMO's or CMP's Medicare enrollees,

other enrollees, and nonenrolled patients, which are typical ''provider'' costs, and costs (such as marketing, enrollment, membership, and operation of the HMO or CMP) that are peculiar to health care prepayment organizations.

(b) *Basic rules.* (1) The allowability of an HMO's or CMP's costs for furnishing services is generally determined in accordance with principles applicable to provider costs, as set forth in § 417.536.

(2) The allowability of other costs is determined in accordance with principles set forth in §§ 417.538 through 417.550.

(3) Costs for covered services for which Medicare is not the primary payor, as described in § 417.528, are not allowable.

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 70 FR 4525, Jan. 28, 2005]

§ 417.536 Cost payment principles.

(a) *Applicability.* Unless otherwise specified in this subpart, the principles set forth in parts 412 and 413 of this chapter are applicable to the costs incurred by an HMO or CMP or by providers and other facilities owned or operated by the HMO or CMP or related to it by common ownership or control. The most common examples of these costs are set forth in this section.

(b) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable cost, in accordance with §§ 413.134, 413.144, and 413.149 of this chapter.

(c) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable cost, in accordance with § 413.153 of this chapter.

(d) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities of a provider or other health care facility owned or operated by an HMO or CMP is an allowable cost in accordance with § 413.85 of this chapter.

(e) *Compensation of owners.* An appropriate amount of compensation for services of owners is an allowable cost, if the services are actually performed and are necessary, as specified in § 413.102 of this chapter.

(f) *Bad debts.* (1) In accordance with § 413.80 of this chapter, bad debts are deductions from revenue and may be included as allowable costs only if—

(i) They are attributable to Medicare deductible and coinsurance amounts for which the Medicare enrollee is liable; and

(ii) The HMO or CMP has made a reasonable, but unsuccessful, effort to collect those amounts.

(2) If all or part of the deductible and coinsurance amounts is payable through a monthly premium or other periodic payment, the amount allowed as a bad debt may not exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent, if the periodic payment is on other than a monthly basis.

(3) Any bad debt related to a service furnished to a Medicare enrollee of the HMO or CMP, and claimed on a cost report submitted for payment by a provider or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the HMO or CMP.

(g) *Charity and courtesy allowances.* As specified in § 413.80 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

(h) *Research costs.* As specified in § 413.90 of this chapter, costs incurred for research purposes, over and above patient care, are not allowable costs.

(i) *Value of services of nonpaid workers.* The value of services of nonpaid workers of an organization is not an allowable cost, except as provided in § 413.94 of this chapter.

(j) *Purchase discounts and allowances and refund of expenses.* Discounts and allowances that an HMO or CMP receives on purchases of goods and services and refunds of previous expense payments must be deducted from the costs to which they relate, in accordance with § 413.98 of this chapter.

(k) *Cost to related entities.* (1) The costs of services, facilities, or supplies furnished to an HMO or CMP by a related entity are allowable at the cost to the related entity in accordance with §413.17 of this chapter.

(2) An entity is not considered related to the HMO or CMP merely because—

(i) It has a risk or incentive agreement under which the HMO or CMP reimburses or compensates the entity for services it furnishes to the HMOs' or CMPs' enrollees; or

(ii) Substantially all the services the entity furnishes are furnished to the HMO's or CMP's enrollees.

(3) However, an entity described in paragraph (k)(2) of this section and an HMO or CMP are considered related if either of them is in a position to exercise significant management or ownership influence or control over the other.

(l) *Return on equity capital of proprietary providers owned by the HMO or CMP.* An allowance for a reasonable return on equity capital invested and used in providing services is allowable in addition to the reasonable cost of services furnished by a proprietary provider owned by the HMO or CMP. The amount of the allowance is determined in accordance with §413.157 of this chapter.

(m) *Limitations on payment.* Medicare payment for covered services furnished by entities owned by or operated by, or related to, an HMO or CMP paid on a reasonable cost basis is subject to certain provisions of parts 412 and 413 of this chapter that pertain to reasonable cost and reasonable charge. Those provisions include, but are not necessarily limited to, the following:

(1) For ESRD treatment, the limitations authorized under §413.170 of this chapter.

(2) For services of physical, occupational, and speech therapists and other therapists and nonphysician health specialists, the limitations set forth in §413.106 of this chapter.

(3) For drugs, the allowable cost as determined under §§405.517 and 410.29 of this chapter.

(4) The overall cost limits established in accordance with §413.30 of this chapter.

(5) The limitation to the lesser of reasonable cost or customary charges, as set forth in §413.13 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§417.538 Enrollment and marketing costs.

(a) *Principle.* Costs incurred by an HMO or CMP in performing the enrollment and marketing activities described in subpart k of this part are allowable.

(b) *Included costs.* Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the HMO's or CMP's plan to potential enrollees in accordance with this part. Those costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(c) *Application.* Enrollment and marketing costs are allowable, whether incurred directly by HMO or CMP staff or under contract with marketing specialists or other outside consultants.

(d) *Limitation on payment.* The relatively higher costs that an HMO or CMP is likely to incur in initially offering its plan to Medicare beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if those costs exceed amounts that would be paid by prudent management, the excess is not allowable.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§417.540 Enrollment costs.

(a) *Principle.* Enrollment costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees.

(b) *Kind of costs included.* Enrollment costs include, but are not limited to, reasonable costs incurred in connection with maintaining statistical, financial, and other data on enrollees.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.542 Reinsurance costs.

Reinsurance costs are not allowable.

§ 417.544 Physicians' services furnished directly by the HMO or CMP.

(a) *Principles.* (1) Compensation paid by an HMO or CMP to physicians is an allowable cost to the extent that it is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or a similar locality.

(2) Physician compensation may take various forms, but the aggregate compensation allowable must be reasonable in relation to the services personally furnished.

(3) If aggregate physician compensation costs exceed what is normally incurred, the excess is not a reasonable cost.

(b) *Application.* (1) In determining the allowability of the costs of physicians' services, the cost of personal services (for example, expenses attributable to salaries, wages, incentive payments, fringe benefits) must be distinguished from the cost of nonpersonal services (for example, expenses attributable to facilities, equipment, support personnel, supplies).

(2) To be allowable, compensation must be reasonable in relation to the personal services furnished.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.546 Physicians' services and other Part B supplier services furnished under arrangements.

General principle. The amount paid by an HMO or CMP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable. Costs are considered reasonable if they—

(a) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(b) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45372, Aug. 31, 1995]

§ 417.548 Provider services through arrangements.

(a) *Principle.* The cost incurred by an HMO or CMP for covered services furnished under arrangement with a provider is allowable to the extent that it would be allowable and payable under parts 412 and 413 of this chapter, unless the HMO or CMP petitions CMS and demonstrates to HFCA's satisfaction that payment in excess of the amount authorized under parts 412 and 413 of this chapter is justified on the basis of advantages gained by the HMO or CMP.

(b) *Application.* An advantage gained must represent a real and tangible benefit received by the HMO or CMP for the excess cost incurred, and any excess payment is subject to other applicable requirements of parts 405, 412 and 413 of this chapter, including tests of reasonableness.

(c) *Example.* In the case of an arrangement an HMO or CMP has with a provider that is located outside the HMO's or CMP's geographic area and that is not related to the HMO or CMP by common ownership or control, payment of the provider's charges to the HMO or CMP (rather than the payment amounts determined under part 412 or part 413 of this chapter) may be justified in exchange for the advantages of not having to incur the administrative costs of determining the provider's reasonable cost and of making a more timely final settlement with the HMO or CMP. However, repayment of the provider's charges would be acceptable only if—

(1) The provider furnishes services to the HMO's or CMP's enrollees infrequently;

(2) The charges represent an insignificant portion of total Medicare reimbursement to the HMO or CMP; and

(3) The charges do not exceed the customary charges by the provider to its other patients for similar services.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.550 Special Medicare program requirements.

(a) *Principle.* CMS pays the full reasonable cost incurred by an HMO or CMP for activities that are solely for

Medicare purposes and unique to Medicare contracts under section 1876 of the Act.

(b) *Application.* CMS pays the full reasonable cost of the following activities:

(1) Reporting increases and decreases in the number of Medicare enrollees.

(2) Obtaining independent certification of the HMO's or CMP's cost report to the extent that it is for Medicare purposes.

(3) Reporting special data that CMS requires solely for program planning and evaluation.

(c) *Prior approval requirement.* The costs specified in paragraph (b) of this section must be separately budgeted and approved by CMS before the contract period begins.

(d) *Limit on full payment.* Full payment is limited to the costs specified in paragraph (b) of this section. All other administrative costs must be apportioned in accordance with § 417.552.

[60 FR 46230, Sept. 6, 1995]

§ 417.552 Cost apportionment: General provisions.

(a) *Basic rule.* The HMO or CMP must apportion its total allowable direct and indirect costs among its Medicare enrollees, its other enrollees, and its nonenrolled patients—

(1) In accordance with this subpart; and

(2) Using methods approved by CMS.

(b) *Purpose of apportionment.* The purpose of apportionment is to ensure that—

(1) The cost of services furnished to Medicare enrollees is not borne by other enrollees and nonenrolled patients; and

(2) The cost of the services furnished to other enrollees and nonenrolled patients is not borne by Medicare.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.554 Apportionment: Provider services furnished directly by the HMO or CMP.

The Medicare share of the cost of covered services furnished to Medicare enrollees by providers that are owned or operated by the HMO or CMP or are related to the HMO or CMP by common ownership or control must be determined in accordance with the apportionment methods set forth in part 412, §§ 413.24, 413.55, and 415.55 of this chapter.

[51 FR 28574, Aug. 8, 1986, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995; 60 FR 63189, Dec. 8, 1995]

§ 417.556 Apportionment: Provider services furnished by the HMO or CMP through arrangements with others.

The Medicare share of the cost of covered services furnished to Medicare enrollees through arrangements with providers other than those specified in § 417.554 must be determined as follows:

(a) The Medicare share must be based on the cost the HMO or CMP pays the provider under their arrangement, to the extent that cost is reasonable and within the limits established by §§ 417.534 through 417.548.

(b) Except as specified in paragraph (c) of this section, apportionment must be on the same approved basis that is used by the provider for Medicare beneficiaries who are not Medicare enrollees of the HMO or CMP, subject to the conditions and limitations set forth in § 417.548.

(c) If, because of the special nature or terms of the HMO's or CMP's arrangement with the provider, apportionment on the basis specified in paragraph (b) of this section would result in Medicare's bearing the costs of furnishing services to individuals other than the HMO's or CMP's Medicare enrollees, apportionment must be on another basis that is approved by CMS and that will ensure that Medicare does not pay any of the cost of furnishing services to individuals who are not Medicare enrollees of the HMO or CMP.

(d) If the HMO or CMP elects to have providers reimbursed by the HMO's or CMP's Medicare intermediary, the Medicare share is the amount the intermediary paid the provider.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.558 Emergency, urgently needed, and out-of-area services for which the HMO or CMP accepts responsibility.

(a) *Source of payment.* Either CMS or the HMO or CMP may pay a provider for emergency or urgently needed services or other covered out-of-area services for which the HMO or CMP accepts responsibility.

(b) *Limits on payment.* If the HMO or CMP pays, the payment amount may not exceed the amount that is allowable under part 412 or part 413 of this chapter.

(c) *Exception to limit on payment.* Payment in excess of the limit imposed by paragraph (b) of this section is allowable only if the HMO or CMP demonstrates to CMS's satisfaction that it is justified on the basis of advantages gained by the HMO or CMP, as set forth in § 417.548.

[60 FR 46231, Sept. 6, 1995]

§ 417.560 Apportionment: Part B physician and supplier services.

(a) *Medical services furnished directly by the HMO or CMP.* The total allowable cost of Part B physician and supplier services furnished by employees or partners of the HMO or CMP or by a related entity of the HMO or CMP must be apportioned on the basis of the ratio of covered Part B services furnished to Medicare enrollees to total services furnished to all the HMO's or CMP's enrollees and nonenrolled patients. The HMO or CMP must use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(b) *Medical services furnished under arrangements made by the HMO or CMP.* When the HMO or CMP pays for Part B physician and supplier services on some basis other than fee-for-service, the reasonable cost the HMO or CMP pays under its financial arrangement with the physician or supplier must be apportioned between Medicare enrollees and others based on the ratio of covered services furnished to Medicare enrollees to the total services furnished to all enrollees and nonenrolled patients. If apportionment on this basis would result in Medicare bearing the cost of furnishing services to individuals who are not Medicare enrollees, the Medicare share must be determined on another basis (approved by CMS) to ensure that Medicare pays only for services furnished to Medicare enrollees.

(c) *Medical services furnished under an arrangement that provides for the HMO or CMP to pay on a fee-for-service basis.* The Medicare share of the cost of Part B physician and supplier services furnished to Medicare enrollees under arrangements, and paid for by the HMO or CMP on a fee-for-service basis, is determined by multiplying the total amount for all such services by the ratio of charges for covered services furnished to Medicare enrollees to the total charges for all such services.

(d) *Emergency services, urgently needed services, and other covered medical services for which the HMO or CMP assumes financial responsibility.* The Medicare share of the cost of Part B emergency or urgently needed services or other Part B services that are not furnished by a provider and for which the HMO or CMP accepts financial responsibility is determined in accordance with paragraphs (b) and (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995]

§ 417.564 Apportionment and allocation of administrative and general costs.

(a) *Costs not directly associated with providing medical care.* Enrollment, marketing, and other administrative and general costs that benefit the total enrollment of the HMO or CMP and are not directly associated with furnishing medical care must be apportioned on the basis of a ratio of Medicare enrollees to the total HMO or CMP enrollment.

(b) *Costs significantly related to providing medical services.* (1) The following administrative and general costs, which bear a significant relationship to the services furnished, are not apportioned to Medicare directly; they must be allocated or distributed to the HMO

or CMP components and then apportioned to Medicare in accordance with §§ 417.552 through 417.560:

(i) Facility costs.

(ii) Interest expense.

(iii) Medical record costs.

(iv) Centralized purchasing costs.

(v) Accounting and data processing costs.

(vi) Other administrative and general costs that are not included in paragraph (a) of this section.

(2) The allocation or distribution process must be as follows:

(i) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which can be quantitatively measured (such as centralized purchasing and data processing), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP in reasonable proportion to the benefits received by these components.

(ii) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which cannot be quantitatively measured (such as facility costs), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP on the basis of a ratio of total incurred and distributed costs per component to the total incurred and distributed costs for all components.

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

(1) Donations.

(2) Fines and penalties.

(3) Political and lobbying activities.

(4) Charity or courtesy allowances.

(5) Spousal education.

(6) Entertainment.

(7) Return on equity.

[60 FR 46231, Sept. 6, 1995, as amended at 75 FR 19803, Apr. 15, 2010]

§ 417.566 Other methods of allocation and apportionment.

(a) *Justification.* A method of apportionment or allocation of costs, other than the methods prescribed in this subpart may be used if it results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint.

(b) *Required approval.* (1) An HMO or CMP that desires to use an alternative method must submit a written request for CMS approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If CMS approves use of a different method, the HMO or CMP may not revert to another method without first obtaining CMS's approval.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.568 Adequate financial records, statistical data, and cost finding.

(a) *Maintenance of records.* (1) An HMO or CMP must maintain sufficient financial records and statistical data for proper determination of costs payable by CMS for covered services the HMO or CMP furnished to its Medicare enrollees either directly or under arrangements with others. These include accurate and sufficient detail of incurred costs and enrollment data.

(2) Unless otherwise provided for in this subpart, the HMO or CMP must follow standardized definitions and accounting, statistics, and reporting practices that are widely accepted in the health care industry.

(b) *Provision of data.* (1) The HMO or CMP must provide adequate cost and statistical data, based on its financial and statistical records, that can be verified by qualified auditors.

(2) The cost data must be based on an approved method of cost finding and, except as provided in paragraph (b)(3) of this section, on the accrual method of accounting.

(3) For governmental institutions that use a cash basis of accounting,

cost data developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the capital asset, is allowable.

(c) *Provider services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes provider services directly, the provider is subject to the cost-finding and cost-reporting requirements set forth in parts 412 and 413 of this chapter. The provider must use an approved cost-finding method described in § 413.24 of this chapter to determine the actual cost of these covered services.

(d) *Supplier services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes Part B physician and supplier services directly, it must furnish statistics that indicate the frequency and type of service provided, in the form and detail prescribed by CMS.

(e) *Part B physician and supplier services furnished through arrangement.* If the HMO or CMP furnishes Part B physician and supplier services under arrangements with others, it must furnish to CMS statistical, financial, and other information with respect to those services in the form and detail prescribed by CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§ 417.570 Interim per capita payments.

(a) *Principle of payment.* (1) CMS makes monthly advance payments equivalent to the HMO's or CMP's interim per capita rate for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(2) Additional lump-sum payments may be made at other times during the contract period, at CMS's discretion, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to the HMO's or CMP's Medicare enrollees, based upon the types and components of costs that are reimbursable under this part. The interim per capita rate is determined annually by CMS on the basis of the HMO's or CMP's annual operating and enrollment forecast (as set forth in § 417.572) and may be revised during the contract period as explained in paragraphs (c) and (d) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, CMS will adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the HMO or CMP in its interim estimated cost and enrollment reports or on other evidence showing that the rate based on actual costs is more or less than the current rate. Adjustments may also be made if there is—

(1) A change in the number of Medicare enrollees that affects the per capita rate;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by the HMO's or CMP's Medicare enrollees.

(d) *Reduction of interim payments.* If the HMO or CMP does not submit, on time, the reports and other data required to determine the proper amount of payment, CMS may reduce interim payments to the extent appropriate, or may take any other action authorized under this part. An interim payment reduction remains in effect until CMS can make a reasonable estimate of per capita costs.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.572 Budget and enrollment forecast and interim reports.

(a) *Annual submittal.* The HMO or CMP must submit an annual operating budget and enrollment forecast, in the form and detail required by CMS, at least 90 days before the beginning of each contract period. The forecast must be based on financial and statistical data and records that can be verified if CMS requires a detailed review of supporting records. The data and records include, but are not limited to, all ledgers, books, records, and original evidence of costs, and statistical data used in the determination of reasonable cost.

(b) *Effect of failure to submit on time.* If the HMO or CMP does not submit the

budget and enrollment forecast on time, CMS may—

(1) Establish an interim per capita rate of payment on the basis of the best available data and adjust payments on the basis of that rate until the required reports are submitted and a new interim per capita rate can be established; or

(2) If there is not enough data on which to base an interim per capita rate, inform the HMO or CMP that interim payments will not be made until the required reports are submitted.

(c) *Interim cost reports.* (1) An HMO or CMP must submit interim cost reports on a quarterly basis in the form and detail prescribed by CMS. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) CMS may reduce the frequency of the reports required under paragraph (c)(1) of this section if CMS determines that, on the basis of the HMO's or CMP's reporting experience, there is good cause to do so.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.574 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the HMO's or CMP's final interim cost and enrollment reports, CMS will make an interim determination of the estimated amount payable to the HMO or CMP for the reasonable cost of covered services furnished to its Medicare enrollees during the contract period. CMS will base the determination on the interim cost report and enrollment data submitted by the HMO or CMP, and any other relevant data CMS finds appropriate. For this purpose, CMS will accept costs as reported, subject to later review or audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments and the amount found payable on the basis of the interim determination under paragraph (a) of this section, must be paid by the HMO or CMP or will be paid by CMS, whichever is appropriate, no later than 30 days after CMS's determination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.576 Final settlement.

(a) *General rule.* Final settlement and payment of amounts due the HMO or CMP or the appropriate Medicare trust funds are made following the HMO's or CMP's submission and CMS's review of an independently certified cost report and supporting documents as described in paragraph (b) of this section.

(b) *Certified cost report as basis for final settlement*—(1) *Timing of cost report.* The HMO or CMP must submit to CMS an independently certified cost report and supporting documents, in the form and detail required by CMS, no later than 180 days after the end of each contract period, unless CMS extends the period for good cause shown by the HMO or CMP.

(2) *Content of cost report.* The cost report and supporting documents must include the following:

(i) The per capita costs incurred in furnishing covered services to its Medicare enrollees, determined in accordance with subpart O of this part and including—

(A) The costs incurred by entities related to the HMO or CMP by common ownership or control; and

(B) For reports for cost-reporting periods that begin on or after January 1, 1996, the costs of hospital and SNF services paid by Medicare's intermediaries under the option provided by §417.532(d).

(ii) The HMO's or CMP's methods of apportioning cost among Medicare enrollees, and nonenrolled patients, in accordance with the payment procedures specified in this subpart (as, applicable, in parts 412 and 413 of this chapter); and

(iii) Any other information required by CMS.

(3) *Failure to report required financial information.* If the HMO or CMP fails to submit the required cost report and supporting documents within 180 days (or an extended period approved by CMS under paragraph (b)(1) of this section), CMS may—

(i) Consider the failure to report as evidence of likely overpayment; and

(ii) Initiate recovery of amounts previously paid, or reduce interim payments, or both.

(c) *Final determination and adjustment.* (1) After receipt of acceptable reports as specified in paragraph (b) of this section, CMS determines the total payment due the HMO or CMP for furnishing covered services to its Medicare enrollees (which is subject to the audit provisions of this subpart) and makes a retroactive adjustment to bring interim payments into agreement with the payable amount due the HMO or CMP.

(2) A final settlement may be made with the HMO or CMP even though a provider that is not owned or operated by the HMO or CMP or related to the HMO or CMP by common ownership or control and that provides services to the HMO's or CMP's Medicare enrollees has not had a final settlement with CMS under parts 412 and 413 of this chapter for services furnished by the provider to Medicare beneficiaries who are not enrolled in the HMO or CMP. In this situation—

(i) CMS must be satisfied that the costs of covered services furnished to the HMO's or CMP's Medicare enrollees, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interest of the Medicare program would best be served by not delaying final settlement with the HMO or CMP until there is a final settlement with the provider for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP; and

(ii) Prompt settlement with the HMO or CMP would be in the best interest of the Medicare program if, for instance, the provider's costs represent an insignificant portion of total payment due to the HMO or CMP; or if CMS is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under parts 412 and 413 of this chapter.

(d) *Notice of amount of payment.* The notice of amount of Medicare payment—

(1) Explains CMS's determination regarding total Medicare payment due the HMO or CMP for the contract period covered by the financial information specified in paragraph (b) of this section;

(2) Relates this determination to the HMO's or CMP's claimed total payable cost for that period;

(3) Explains the amounts and reasons, by appropriate reference to law, regulations, and Medicare program policy and procedures, if the determined amounts differ from the HMO's or CMP's claim; and

(4) Informs the HMO or CMP of its right to a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter

(e) *Basis for retroactive adjustment.* (1) CMS's determination (as contained in the notice of amount of Medicare payment) constitutes the basis for making retroactive adjustments to any Medicare payment made to the HMO or CMP during the period to which the determination applies.

(2) Further payments to the HMO or CMP may be withheld or offset in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO or CMP, even if the HMO or CMP requests a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(3) Any withholding continues until the earliest of the following occurs:

(i) The overpayment is liquidated.

(ii) The HMO or CMP enters into an agreement with CMS to refund the overpaid amount.

(iii) CMS, on the basis of subsequently acquired information, determines that there was no overpayment.

(iv) The decision of a hearing specified in paragraph (d)(4) of this section is that there was no overpayment.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995; 60 FR 46231, Sept. 6, 1995; 73 FR 30267, May 23, 2008]

Subpart P—Medicare Payment: Risk Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.580 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1876 (a), (e), and (g) of the Act that pertain to the

amount CMS pays an organization for its Medicare enrollees who are enrolled on a risk basis.

(b) *Scope.* This subpart sets forth—

(1) Method of payment;

(2) Procedures for determining the HMO's or CMP's payment rate; and

(3) Procedures for determining the additional benefits (and their value) the HMO or CMP must provide to its Medicare enrollees.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§417.582 Definitions.

As used in this subpart—

AAPCC stands for adjusted average per capita cost.

ACR stands for adjusted community rate.

Actuarial factors means factors such as the age, sex, and disability level distribution of the population and any other relevant factors that CMS determines have a significant effect on the level of utilization and cost of health services.

APCRP stands for average of per capita rates of payment.

Class of Medicare enrollees means a group of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.

Similar area means an area similar to the HMO's or CMP's geographic area but free from special characteristics that would distort the determination of the AAPCC.

U.S. per capita incurred cost means the average per capita cost, including intermediary or carrier administrative costs, incurred by Medicare, as determined on an accrual basis, for covered services furnished to Medicare beneficiaries nationwide during the most recent period for which CMS has complete data.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.584 Payment to HMOs or CMPs with risk contracts.

Except in the circumstances specified in §417.440(d) for inpatient hospital care, and as provided in §417.585 for hospice care, CMS makes payment for covered services only to the HMO or CMP.

(a) *Principle of payment.* CMS makes monthly advance payments equivalent to the HMO's or CMP's per capita rate of payment for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(b) *Determination of rate.* (1) The annual per capita rate of payment for each class of Medicare enrollees is equal to 95 percent of the AAPCC (as determined under the provisions of §417.588) for that class of Medicare enrollees.

(2) CMS furnishes each HMO or CMP with its per capita rate of payment for each class of Medicare enrollees not later than 90 days before the beginning of the HMO's or CMP's contract period.

(c) *Adjustments to payments.* If the actual number of Medicare enrollees differs from the estimated number on which the amount of advance monthly payment was based, CMS adjusts subsequent monthly payments to take account of the difference.

(d) *Reduction of payments.* If an HMO or CMP requests a reduction in its monthly payment in accordance with §417.592(b)(2), CMS reduces the amount of payment by the appropriate amount.

(e) *Determination of rate for calendar year 1998.* For calendar year 1998, HMOs or CMPs with risk contracts will be paid in accordance with principles contained in subpart F of part 422 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995; 63 FR 35067, June 26, 1998]

§417.585 Special rules: Hospice care.

(a) No payment is made to an HMO or CMP on behalf of a Medicare enrollee who has elected hospice care under §418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in §417.592. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the enrollee resumes normal Medicare coverage.

(b) During the time the election is in effect, the HMO or CMP may bill CMS

on a fee-for-service basis (subject to the usual Medicare rules of payment) but only for the following covered Medicare services:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which the enrollee elected hospice care or a condition related to the terminal condition.

(3) Services furnished after the revocation or expiration of the enrollee's hospice election until the full monthly capitation payments begin again.

(c) Payment for hospice care services furnished to Medicare enrollees of an HMO or CMP is made to the Medicare-participating hospice elected by the enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.588 Computation of adjusted average per capita cost (AAPCC).

(a) *Basic data.* In computing the AAPCC, CMS uses the U.S. per capita incurred cost and adjusts it by the factors specified in paragraph (c) of this section to establish an AAPCC for each class of Medicare enrollees.

(b) *Advance notice to the HMO or CMP.* Before the beginning of a contract period, CMS informs the HMO or CMP of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors*—(1) *Geographic.* CMS makes an adjustment to reflect the relative level of Medicare expenditures for beneficiaries who reside in the HMO's or CMP's geographic area (or a similar area). This adjustment is based on reimbursement for Medicare covered services and uses the most accurate and timely data that pertain to the HMO's or CMP's geographic area and that is available to CMS when it makes the determination.

(2) *Enrollment.* CMS makes a further adjustment to remove the cost effect of all area Medicare beneficiaries who are enrolled in the HMO or CMP or another HMO or CMP.

(3) *Age, sex, and disability status.* CMS makes adjustments to reflect the age and sex distribution and the disability status of the HMO's or CMP's enrollees based on Medicare program experience and available data that indicate cost differences that result from those factors.

(4) *Other relevant factors.* If accurate data are available and appropriate, CMS makes adjustments to reflect welfare and institutional status and other relevant factors.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.590 Computation of the average of the per capita rates of payment.

(a) *Computation by the HMO or CMP.* As indicated in § 417.584(b), before an HMO's or CMP's contract period begins, CMS determines a per capita rate of payment for each class of the HMO's or CMP's Medicare enrollees. In order to determine the additional benefits required under § 417.592, weighted averages of those per capita rates must be computed separately for enrollees entitled to Part A and Part B, and for enrollees entitled only to Part B. Except as provided in paragraph (b) of this section, the HMO or CMP must make the computations.

(b) *Computation by CMS.* If the HMO or CMP claims to have insufficient enrollment experience to make the computations required by paragraph (a) of this section, and CMS agrees with the claim, CMS makes the computations, using the best available information, which may include the enrollment experience of other risk HMOs and CMPs.

[58 FR 38075, July 15, 1993]

§ 417.592 Additional benefits requirement.

(a) *General rules.* (1) An HMO or CMP that has an APCRP (as determined under § 417.590) greater than its ACR (as determined under § 417.594) must elect one of the options specified in paragraph (b) of this section.

(2) The dollar value of the elected option must, over the course of a contract period, be at least equal to the difference between the APCRP and the proposed ACR.

(b) *Options*—(1) *Additional benefits.* Provide its Medicare enrollees with additional benefits in accordance with paragraph (c) of this section.

(2) *Payment reduction.* Request CMS to reduce its monthly payments.

(3) *Combination of additional benefits and payment reduction.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section and request CMS to reduce the monthly payments by the remaining difference between the APCRP and the ACR.

(4) *Combination of additional benefits and withholding in a stabilization fund.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section, and request CMS to withhold in a stabilization fund (as provided in §417.596) the remaining difference between the APCRP and the ACR.

(c) *Special rules: Additional benefits option.* (1) The HMO or CMP must determine additional benefits separately for enrollees entitled to both Part A and Part B benefits and those entitled only to Part B.

(2) The HMO or CMP may elect to provide additional benefits in any of the following forms—

(i) A reduction in the HMO's or CMP's premium or in other charges it imposes in the form of deductibles or coinsurance.

(ii) Health benefits in addition to the required Part A and Part B covered services.

(iii) A combination of reduced charges and additional benefits.

(d) *Notification to CMS.* (1) The HMO or CMP must give CMS notice of its ACR and its weighted APCRP at least 45 days before its contract period begins.

(2) An HMO or CMP that elects the option of providing additional benefits must include in its submittal—

(i) A description of the additional benefits it will provide to its Medicare enrollees; and

(ii) Supporting evidence to show that the selected benefits meet the requirements of paragraph (a)(2) of this section with respect to dollar value equivalence.

[60 FR 46232, Sept. 6, 1995]

§417.594 Computation of adjusted community rate (ACR).

(a) *Basic rule.* Each HMO or CMP must compute its basic rate as follows:

(1) Compute an initial rate in accordance with paragraph (b) of this section.

(2) Adjust and reduce the initial rate in accordance with paragraphs (c) and (d) of this section.

(b) *Computation of initial rates.* (1) The HMO or CMP must compute its initial rate using either of the following systems:

(i) A community rating system as defined in §417.104(b); or

(ii) A system, approved by CMS, under which the HMO or CMP develops an aggregate premium for all its enrollees and weights the aggregate by the size of the various enrolled groups that compose its enrollment.

(For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers that enroll in the HMO or CMP through payment of premiums.)

(2) Regardless of which method the HMO or CMP uses—

(i) The initial rate must be equal to the premium it would charge its non-Medicare enrollees for the Medicare-covered services;

(ii) The HMO or CMP must compute the rates separately for enrollees entitled to Medicare Part A and Part B and for those entitled only to Part B; and

(iii) The HMO or CMP must identify and take into account anticipated revenue from health insurance payers for those services for which Medicare is not the primary payer as provided in §417.528.

(3) Except as provided in paragraph (b)(4) of this section, the HMO or CMP must identify in its initial rate calculation, the following components whose rates must be consistent with rates used by the HMO or CMP in calculating premiums for non-Medicare enrollees:

(i) Hospital services (services covered under Medicare Part A and Part B shown separately).

(ii) Physicians' services.

(iii) Other medical services (for example, X-ray and laboratory services).

(iv) Home health services.

(v) Out-of-plan claims for emergency services.

(vi) Skilled nursing care services.

(vii) Ambulance services.

(viii) Other Medicare covered services.

(ix) General and administrative.

(x) Noncovered Medicare services (for example, eyeglasses).

(xi) Services for which Medicare is the secondary payer.

(xii) Enrollee liabilities (for example, deductibles, coinsurance, or copayments) for covered services.

(4) An HMO or CMP that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the HMO or CMP provides CMS with the documentation necessary to support any adjustments the HMO or CMP makes to the initial rate in accordance with paragraph (e) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the HMO or CMP during prior contract periods. The HMO or CMP must submit supporting documentation to assure CMS that rates do not include past losses but only premiums for the price of additional benefits and services of the upcoming contract period.

(c) *Adjustment of initial rates*—(1) *Purpose of adjustment.* The purpose of adjustment is to reflect the utilization characteristics of Medicare enrollees.

(2) *Adjustment by the HMO or CMP.* The HMO or CMP may adjust the rate for a particular service using more than one of the following factors if they do not duplicate each other:

(i) *Unit of service.* If the HMO or CMP purchases or identifies services on a unit of service basis and the unit of service is defined the same for all enrollees, the HMO or CMP may make an adjustment in its initial rate to reflect the number of units of services furnished to its Medicare enrollees in comparison to those furnished to other enrollees.

(ii) *Complexity or intensity of services.* The HMO or CMP may make an adjustment to reflect the differences in the complexity or intensity of services furnished to its Medicare enrollees if the calculation of its initial rate includes the elements of this adjustment.

(3) *Support documentation.* All adjustments made by the HMO or CMP must be accompanied by adequate supporting data. If an HMO or CMP does not have sufficient enrollment experience to develop this data, it may, during its initial contract period, use documented statistics from a nationally recognized statistical source.

(4) *Adjustment by CMS.* If the HMO or CMP does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of its Medicare enrollees, CMS will, at the HMO's or CMP's request, adjust the initial rate. CMS adjusts the rate on the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other HMOs or CMPs; or

(ii) Medicare beneficiaries (in the HMO's or CMP's area, or State, or the United States) who are eligible to enroll in an HMO or CMP and other individuals in that same area, or State, or the United States.

(d) *Reduction of adjusted rates.* The HMO or CMP or CMS further reduces the adjusted rates by the actuarial value of applicable Medicare deductibles and coinsurance.

(e) *CMS review*—(1) *Submission of data.* The HMO or CMP must submit its ACR and the methodology used to compute it for CMS review and approval, and must include adequate supporting data.

(2) *Appeals procedures.* (i) If CMS determines that an HMO's or CMP's ACR computation is not acceptable, the HMO or CMP may, within 30 days after receipt of notice of the determination, file with CMS a request for a hearing.

(ii) The request must state why the HMO or CMP believes the determination is incorrect, and include any supporting evidence the HMO or CMP considers pertinent.

(iii) A hearing officer designated by CMS conducts the hearing in accordance with the hearing procedures set forth in §§ 405.1819 through 405.1833 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.596 Establishment of a benefit stabilization fund.

(a) *General.* If an HMO or CMP is required to provide its Medicare enrollees with additional benefits as described in §417.592, the organization may request that CMS withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

(b) *Notification to CMS.* An HMO's or CMP's request to have monies withheld in a benefit stabilization fund must be made when the HMO or CMP notifies CMS under §417.592(d) of its ACR and its APCRP in preparation for its next contract period.

(c) *Limitations on the amounts withheld*—(1) *Limit per contract period.* Except as provided in paragraph (c)(3) of this section, CMS does not withhold in a benefit stabilization fund more than 15 percent of the difference between an HMO's or CMP's ACR and its ACPRP for a given contract period.

(2) *Cumulative limit.* If CMS has established a benefit stabilization fund for an HMO or CMP, it does not approve a request for withholding made by that HMO or CMP for a subsequent contract period that would cause the total value of the benefit stabilization fund to exceed 25 percent of the difference between the HMO's or CMP's ACR and the average of its per capita rates of payment for that subsequent contract period.

(3) *Exception.* CMS may grant an exception to the limit described in paragraph (c)(1) of this section if an HMO or CMP can demonstrate to CMS's satisfaction that the value of the additional benefits it provides to its Medicare enrollees fluctuates substantially in excess of 15 percent from one contract period to another.

(d) *Financial management of benefit stabilization funds.* (1) The amounts withheld by CMS to establish and maintain a benefit stabilization fund are in the custody of the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

(2) The amounts withheld in a benefit stabilization fund are accounted for by CMS in accounts in which interest does not accrue to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended by 56 FR 46571, Sept. 13, 1991; 58 FR 38083, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

§417.597 Withdrawal from a benefit stabilization fund.

(a) *Notification to CMS.* An HMO's or CMP's request to make a withdrawal from its benefit stabilization fund for use during a contract period must be made when the HMO or CMP notifies CMS of its ACR and its ACPRP for that contract period. In making its request, the HMO or CMP must—

(1) Indicate how it intends to use the withdrawn amounts;

(2) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(3) Document the HMO's or CMP's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(4) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the HMO or CMP will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(b) *Criteria for CMS approval.* CMS approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(1) The HMO's or CMP's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The HMO's or CMP's ACR for the next contract period is significantly higher than that of the previous contract period; or

(3) The HMO's or CMP's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period.

(c) *Basis for denial.* CMS does not approve a request for a withdrawal from a benefit stabilization fund if the withdrawal would allow the HMO or CMP to—

(1) Offer without charge the supplemental services it provides to its Medicare enrollees under the provisions of § 417.440 (b)(2) or (b)(3); or

(2) Refinance prior contract period losses or to avoid losses in the upcoming contract period.

(d) *Form of payment.* Payment of monies withdrawn from a benefit stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the HMO or CMP under § 417.584 during the period of the contract.

[58 FR 38075, July 15, 1993, as amended at 60 FR 46233, Sept. 6, 1995]

§ 417.598 Annual enrollment reconciliation.

CMS's payment to an HMO or CMP may be subject to an enrollment reconciliation at least annually. CMS conducts this reconciliation as necessary to ensure that the payments made do not exceed or fall short of the appropriate per capita rate of payment for each Medicare enrollee of the HMO or CMP during the contract period. The HMO or CMP must submit any information or reports required by CMS to conduct the reconciliation.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

Subpart Q—Beneficiary Appeals

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

[60 FR 46233, Sept. 6, 1995, as amended at 62 FR 23374, Apr. 30, 1997; 70 FR 4713, Jan. 28, 2005]

Subpart R—Medicare Contract Appeals

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.640 Applicability.

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

[75 FR 19803, Apr. 15, 2010]

Subparts S–T [Reserved]

Subpart U—Health Care Prepayment Plans

SOURCE: 50 FR 1375, Jan. 10, 1985, unless otherwise noted.

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions.* As used in this subpart, unless the context indicates otherwise—

Covered Part B services means physicians' services, diagnostic X-ray tests, laboratory, other diagnostic tests, and any additional medical and other

health services, that the HCPP furnishes to its Medicare enrollees.

Health care prepayment plan (HCPP) means an organization that meets the following conditions:

(1) Effective January 1, 1999, (or on the effective date of the HCPP agreement in the case of a 1998 applicant) either—

(A) Is union or employer sponsored; or

(B) Does not provide, or arrange for the provision of, any inpatient hospital services.

(2) Is responsible for the organization, financing, and delivery of covered Part B services to a defined population on a prepayment basis.

(3) Meets the conditions specified in paragraph (b) of this section.

(4) Elects to be reimbursed on a reasonable cost basis.

Medicare enrollee means a beneficiary under Part B of Medicare who has been identified on CMS records as an enrollee of the HCPP. *Reporting period* means the period specified by CMS for which an HCPP must report its costs and utilization.

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with CMS as specified in §417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of title XVIII of the Social Security Act and section 353 of the PHS Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would not otherwise meet the conditions specified in paragraph (b)(1) of this section, may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with CMS as required by §417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, CMS pays an HCPP on the basis of the reasonable cost it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(2) *Payment for Part B services: Basic rules*—(i) *Cost basis payment.* Except as provided in paragraph (d) of this section, CMS pays an HCPP on the basis of the reasonable costs it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(ii) *Deductions.* In determining the amount due an HCPP for covered Part B services furnished to its Medicare enrollees, CMS deducts, from the reasonable cost actually incurred by the HCPP, the following:

(A) The actuarial value of the Part B deductible.

(B) An amount equal to 20 percent of the cost incurred for any service that is subject to the Medicare coinsurance.

(d) *Covered services not reimbursed to an HCPP.* (1) Services reimbursed under Part A are not reimbursable to an HCPP. CMS makes payment for these services directly to the hospital, or other provider of services, on a reasonable cost basis through the provider's Medicare fiscal intermediary (for more details, see parts 412 and 413 of this chapter).

(2) Covered Part B services furnished by a provider of services to an HCPP's Medicare enrollees are not payable to the HCPP. CMS makes payment for these services to the provider on behalf of the Medicare enrollee through the provider's Medicare fiscal intermediary. This requirement does not affect Medicare payment to the HCPP for physicians' services furnished to its Medicare enrollees for which the physicians are compensated by the HCPP.

(e) *Payment for services to nonenrollees.* CMS makes payment to an HCPP for covered Part B services furnished by the HCPP to a Medicare beneficiary who is not enrolled in the HCPP if the beneficiary assigns his rights to payment in accordance with §424.55 of this

chapter. Payment is made on a reasonable charge basis through the HCPP's Medicare carrier.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 7135, Feb. 28, 1992; 58 FR 38081, July 15, 1993; 60 FR 34888, July 5, 1995; 63 FR 35067, June 26, 1998; 63 FR 52611, Oct. 1, 1998]

§ 417.801 Agreements between CMS and health care prepayment plans.

(a) *General requirement.* (1) In order to participate and receive payment under the Medicare program as an HCPP as defined in § 417.800, an organization must enter into a written agreement with CMS.

(2) An existing group practice prepayment plan (GPPP) that continues as an HCPP under this subpart U must have entered into a written agreement with CMS within 60 days of January 31, 1983.

(b) *Terms.* The agreement must provide that the HCPP agrees to—

(1) Maintain compliance with the requirements for participation and reimbursement on a reasonable cost basis of HCPPs as specified in § 417.800;

(2) Not charge the Medicare enrollee or any other person for items or services for which that enrollee is entitled to have payment made under the provisions of this part, except for any deductible or coinsurance amounts for which the enrollee is liable;

(3) Refund, as promptly as possible, any money incorrectly collected as charges or premiums, or in any other way from Medicare enrollees in the HCPP in accordance with the requirements specified in § 417.456;

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Meet the advance directives requirements specified in § 417.436(d) of this part;

(6) Establish administrative review procedures in accordance with §§ 417.830 through 417.840 for Medicare enrollees who are dissatisfied with denied services or claims; and

(7) Consider any additional requirements that CMS finds necessary or desirable for efficient and effective program administration.

(c) *Duration of agreement.* Except for the term of the initial agreement, the agreement is for a term of one year and may be renewed annually by mutual consent. The term of the initial agreement is set by CMS.

(d) *Termination or nonrenewal of agreement by CMS.* (1) CMS may terminate or not renew an agreement if it determines that—

(i) The HCPP no longer meets the requirements for participation and reimbursement as an HCPP as specified in § 417.800;

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law. This includes, but is not limited to, the following:

(A) Failure to provide for and document adequate access to providers.

(B) Failure to comply with CMS requirements concerning provision of data and maintenance of records.

(C) Failure to comply with financial requirements specified at § 417.806; or

(iii) The HCPP undergoes a change in ownership as specified in subpart M of this part.

(2) CMS will give notice of termination or nonrenewal to the HCPP at least 90 days before the effective date stated in the notice.

(e) *Termination or nonrenewal of agreement by HCPP.* (1) If an HCPP does not wish to renew its agreement at the end of the term, it must give written notice to CMS at least 90 days before the end of the term of the agreement. If an HCPP wishes to terminate its agreement before the end of the term, it must file a written notice with CMS stating the intended effective date of termination.

(2) CMS may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. CMS makes this decision based on a finding that termination on a specific date would not—

(i) Unduly disrupt the furnishing of services to the community serviced by the HCPP; or

(ii) Otherwise interfere with the efficient administration of the Medicare program.

[50 FR 1375, Jan. 10, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38081, July 15, 1993; 59 FR 49843, Sept. 30, 1994; 59 FR 59943, Nov. 21, 1994; 77 FR 22166, Apr. 12, 2012]

§ 417.802 Allowable costs.

(a) *General rule.* The costs that are considered allowable for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs specified in subpart O of this part, except those in §§ 417.531, 417.532 (a)(3) and (c) through (g), 417.536 (l) and (m), 417.546, 417.548, and 417.550(b)(2).

(b) *Physicians' services and other Part B supplier services furnished under arrangements*—(1) *Principle.* The amount paid by an HCPP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable.

(2) *Application: Payment on other than a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the HCPP may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the HCPP makes payment compensates its physicians on a fee-for-service basis, the HCPP's payment to the group may not exceed the reasonable charges for those services, as defined in subpart E of part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(2)(ii)(A) of this section is allowable if the group has procedures under which members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

(3) *Application: Payment on a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(3)(ii) of this section, the costs incurred by the HCPP are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in subpart E of part 405 of this chapter; and

(B) The amount that CMS would pay for those services if they were furnished to beneficiaries who are not enrolled in the HCPP and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the paragraph (b)(3)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In these cases, the amount paid by an HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.804 Cost apportionment.

(a) The HCPP follows the cost apportionment principles specified in §§ 417.552 through 417.566, except for provisions on provider costs and provisions on departmental apportionment.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

§ 417.806 Financial records, statistical data, and cost finding.

(a) The principles specified in § 417.568 apply to HCPPs, except those in paragraph (c) of that section.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(c) An HCPP must permit the Department and the Comptroller General to audit or inspect any books and records of the HCPP and of any related organization that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees. For purposes of this requirement, the principles specified in § 417.486 apply to HCPPs.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.808 Interim per capita payments.

The HCPP follows the principles specified in §§ 417.570 and 417.572 on interim per capita payments, except for the following:

(a) When applying these principles to HCPPs, the term ''reporting period'' should be used instead of the term ''contract period'' contained in that section.

(b) An HCPP must submit to CMS an annual operating budget and enrollment forecast, in the form and detail specified by CMS, at least 60 days before the beginning of each reporting period. A reporting period must be 12 consecutive months, except that the HCPP's initial reporting period for participating in Medicare may be as short as 6 months or as long as 18 months.

(c) An HCPP must submit to CMS an interim cost report and enrollment data applicable to the first 6-month period of the HCPP's reporting period in the form and detail specified by CMS. The interim cost report must be submitted not later than 45 days after the close of the first 6-month period of the HCPP's reporting period.

(d) In lieu of an interim payment based on the actual monthly enrollment in an HCPP, CMS and the HCPP may agree to a uniform monthly interim reimbursement rate for a reporting period. This interim rate is based on the HCPP's budget and enrollment forecast, if CMS is satisfied that the rate is consistent with efficiency and economy, and will not result in excessive adjustment at the end of the reporting period.

§ 417.810 Final settlement.

(a) *General requirement.* CMS and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to CMS, following the submission and review of the HCPP's annual cost report and the supporting documents specified in paragraph (b) of this section.

(b) *Annual cost report as basis for final settlement*—(1) *Form and due date.* An HCPP must submit to CMS a cost report and supporting documents in the form and detail specified by CMS, no later than 120 days following the close of a reporting period.

(2) *Contents.* The report must include—

(i) The HCPP's per capita incurred costs of providing covered Part B services to its Medicare enrollees during the reporting period, including any costs incurred by another organization related to the HCPP by common ownership or control;

(ii) The HCPP's methods of apportioning costs among its Medicare enrollees, enrollees who are not Medicare beneficiaries, and other nonenrollees, including Medicare beneficiaries receiving health care services on a fee-for-service or other basis; and

(iii) Information on enrollment and other data as specified by CMS.

(3) *Extension of time to submit cost report.* CMS may grant an HCPP an extension of time to submit a cost report for good cause shown.

(4) *Failure to report required financial information.* If an HCPP does not submit the required cost report and supporting documents within the time specified in paragraph (b)(1) of this section, and has not requested and received an extension of time for good cause shown, CMS may—

(i) Regard the failure to report this information as evidence of likely overpayment and reduce or suspend interim payments to the HCPP; and

(ii) Determine that amounts previously paid are overpayments, and make appropriate recovery.

(c) *Determination of final settlement.* Following the HCPP's submission of

the reports specified in paragraph (b) of this section in acceptable form, CMS makes a determination of the total reimbursement due the HCPP for the reporting period and the difference, if any, between this amount and the total interim payments made to the HCPP. CMS sends to the HCPP a notice of the amount of reimbursement by the Medicare program. This notice—

(1) Explains CMS's determination of total reimbursement due the HCPP for the reporting period; and

(2) Informs the HCPP of its right to have the determination reviewed at a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(d) *Payment of amounts due.* (1) Within 30 days of CMS's determination, CMS or the HCPP, as appropriate, will make payment of any difference between the total amount due and the total interim payments made to the HCPP by CMS.

(2) If the HCPP does not pay CMS within 30 days of CMS's determination of any amounts the HCPP owes CMS, CMS may offset further payments to the HCPP to recover, or to aid in the recovery of, any overpayment identified in its determination.

(3) Any offset of payments CMS makes under paragraph (d)(2) of this section will remain in effect even if the HCPP has requested a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(e) *Tentative settlement.* (1) If a final settlement cannot be made within 90 days after the HCPP submits the report specified in paragraph (b) of this section, CMS will make an interim settlement by estimating the amount payable to the HCPP.

(2) CMS or the HCPP will make payment within 30 days of CMS's determination under the tentative settlement of any estimated amounts due.

(3) The tentative settlement is subject to adjustment at the time of a final settlement.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993; 73 FR 30267, May 23, 2008]

§ 417.830 Scope of regulations on beneficiary appeals.

Sections 417.832 through 417.840 establish procedures for the presentation and resolution of organization determinations, reconsiderations, hearings, Departmental Appeals Board review, court reviews, and finality of decisions that are applicable to Medicare enrollees of an HCPP.

[59 FR 59943, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 417.832 Applicability of requirements and procedures.

(a) The administrative review rights and procedures specified in §§ 417.834 through 417.840 pertain to disputes involving an organization determination, as defined in § 417.838, with which the enrollee is dissatisfied.

(b) Physicians and other individuals who furnish items or services under arrangements with an HCPP have no right of administrative review under §§ 417.834 through 417.840.

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

[59 FR 59943, Nov. 21, 1994, as amended at 70 FR 4713, Jan. 28, 2005]

§ 417.834 Responsibility for establishing administrative review procedures.

The HCPP is responsible for establishing and maintaining the administrative review procedures that are specified in §§ 417.830 through 417.840.

[59 FR 59943, Nov. 21, 1994]

§ 417.836 Written description of administrative review procedures.

Each HCPP is responsible for ensuring that all Medicare enrollees are informed in writing of the administrative review procedures that are available to them.

[59 FR 59943, Nov. 21, 1994]

§ 417.838 Organization determinations.

(a) *Actions that are organization determinations.* For purposes of §§ 417.830 through 417.840, an organization determination is a refusal to furnish or arrange for services, or reimburse the

party for services provided to the beneficiary, on the grounds that the services are not covered by Medicare.

(b) *Actions that are not organization determinations.* The following are not organization determinations for purposes of §§ 417.830 through 417.840:

(1) A determination regarding services that were furnished by the HCPP, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding services that are not covered under the HCPP's agreement with CMS.

[59 FR 59943, Nov. 21, 1994]

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.626 of this chapter to—

(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and

(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

[75 FR 19803, Apr. 15, 2010]

Subpart V—Administration of Outstanding Loans and Loan Guarantees

§ 417.910 Applicability.

The regulations in this subpart apply, as appropriate, to public and private entities that have loans or loan guarantees that—

(a) Were awarded to them before October 1986 under section 1304 or section 1305 of the PHS Act; and

(b) Are still outstanding.

[59 FR 49842, Sept. 30, 1994]

§ 417.911 Definitions.

As used in this subpart—

Any 12-month period means the 12-month period beginning on the first day of any month.

Expansion of services means—

(1) The addition of any health service not previously provided by or through the HMO, that requires an increase in the facilities, equipment, or health professionals of the HMO; or

(2) The improvement or upgrading of existing facilities or equipment, or an increase in the number of categories of health professionals, of the HMO so that the HMO could provide directly services that it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

First 60 months of operation or expansion means the 60-month period beginning on the first day of the month during which the HMO first provided services to enrollees, or in the case of significant expansion, first provided services in accordance with its expansion plan.

Health system agency means an entity that has been designated in accordance with section 1515 of the PHS Act; and the term *State health planning and development agency* means an agency that has been designated in accordance with section 1521 of the PHS Act.

Initial costs of operation means any cost incurred in the first 60 months of an operation or expansion that met any of the following requirements:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority, was not a capital cost.

(2) Was required by State regulatory authority to meet reserves or tangible net equity requirements.

(3) Was for a payment made to reduce balance sheet liabilities existing at the beginning of the 60-month period, but only if—

(i) The payment had been approved in writing by the Secretary; and

(ii) The total of these payments did not exceed 20 percent of the amount of the loan.

(4) Was for a small capital expenditure, but only if—

(i) The cost had been approved in writing by the Secretary; and

(ii) The total of these costs did not exceed $200,000 in any 12-month period, and $400,000 during the first 60 months of operation or expansion.

Nonprofit as applied to a private entity, means a private agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Significant expansion means—

(1) A planned substantial increase in the enrollment of the HMO, that requires an increase in the number of health professionals serving enrollees of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or

(2) A planned expansion of the service area beyond the current service area, that would be made possible by the addition of health service delivery facilities and health professionals to serve enrollees at a new site or sites in areas previously without service sites.

Small capital expenditure means expenditures for—

(1) Equipment as defined in 45 CFR 74.132; or

(2) Alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

[58 FR 38076, July 15, 1993, as amended at 59 FR 49842, Sept. 30, 1994]

§ 417.920 Planning and initial development.

(a) Under section 1304 of the PHS Act, grants and loan guarantees were awarded for projects for planning and initial development of HMOs.

(b) Planning projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(c) Initial development projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(3) Expansion of the range or amount of services furnished by the HMO.

[58 FR 38076, July 15, 1993]

§ 417.930 Initial costs of operation.

Under section 1305 of the PHS, loans and loan guarantees were awarded for initial costs of operation of HMOs.

[58 FR 38077, July 15, 1993]

§ 417.931 [Reserved]

§ 417.934 Reserve requirement.

(a) *Timing.* Unless the Secretary approved a longer period, an entity that received a loan or loan guarantee under section 1305 of the PHS Act was required to establish a restricted reserve account on the earlier of the following:

(1) When the HMO's revenues and costs of operation reached the breakeven point.

(2) At the end of the 60-month period following the Secretary's endorsement of the loan or loan guarantee.

(b) *Purpose and amount of reserve.* The reserve had to be constituted so as to accumulate, no later than 12 years after endorsement of the loan or loan guarantee, an amount equal to 1 year's principal and interest.

[59 FR 49842, Sept. 30, 1994]

§ 417.937 Loan and loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart was disbursed to the entity in accordance with an agreement entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, is repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary could approve a shorter repayment period if he or she determined that a repayment period of less than 22 years is more appropriate to an entity's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon is repayable in accordance with a repayment schedule that is agreed upon by the parties to the loan or loan guarantee and approved by the Secretary before or at the time of endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary is repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient in

amount to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation could be deferred with payment of interest only during that period. The Secretary could set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date of disbursement for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[59 FR 49842, Sept. 30, 1994]

§ 417.940 Civil action to enforce compliance with assurances.

The provisions of § 417.163(g) apply to entities that have outstanding loans or loan guarantees administered under this subpart.

[59 FR 49843, Sept. 30, 1994]

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 56026, Dec. 16, 1983, unless otherwise noted.

Subpart A—General Provision and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act (the Act). Section 1861(dd) of the Act specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. Section 1861(dd) also specifies limitations on coverage of, and payment for, inpatient hospice care. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(7) and 1814(i) of the Act contain conditions and limitations on coverage of, and payment for, hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

[48 FR 56026, Dec. 16, 1983, as amended at 57 FR 36017, Aug. 12, 1992; 74 FR 39413, Aug. 6, 2009]

§ 418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility and election requirements and the benefit periods. Subparts C and D specify the conditions of participation for hospices. Subpart E is reserved for future use. Subparts F and G specify coverage and payment policy. Subpart H specifies coinsurance amounts applicable to hospice care.

[74 FR 39413, Aug. 6, 2009]

§ 418.3 Definitions.

For purposes of this part—

Attending physician means a—

(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education, and experience requirements as described in § 410.75 (b) of this chapter.

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

Cap period means the twelve-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

Clinical note means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.

Comprehensive assessment means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Dietary counseling means education and interventions provided to the patient and family regarding appropriate

nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.

Employee means a person who:

(1) Works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf;

(2) If the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or

(3) Is a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

Initial assessment means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

Physician designee means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available.

Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.

Restraint means—(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or

(2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

Social worker means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 50 FR 50834, Dec. 11, 1990; 70 FR 45144, Aug. 4, 2005; 72 FR 50227, Aug. 31, 2007; 73 FR 32204, June 5, 2008]

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

(1) An initial 90-day period;

(2) A subsequent 90-day period; or

(3) An unlimited number of subsequent 60-day periods.

(b) The periods of care are available in the order listed and may be elected separately at different times.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 70546, Nov. 22, 2005]

§ 418.22 Certification of terminal illness.

(a) *Timing of certification*—(1) *General rule.* The hospice must obtain written certification of terminal illness for each of the periods listed in § 418.21, even if a single election continues in effect for an unlimited number of periods, as provided in § 418.24(c).

(2) *Basic requirement.* Except as provided in paragraph (a)(3) of this section, the hospice must obtain the written certification before it submits a claim for payment.

(3) *Exceptions.* (i) If the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(ii) Certifications may be completed no more than 15 calendar days prior to the effective date of election.

(iii) Recertifications may be completed no more than 15 calendar days prior to the start of the subsequent benefit period.

(4) *Face-to-face encounter.* As of January 1, 2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice patient whose total stay across all hospices is anticipated to reach the 3rd benefit period. The face-to-face encounter must occur prior to, but no more than 30 calendar days prior to, the 3rd benefit period recertification, and every benefit period recertification thereafter, to gather clinical findings to determine continued eligibility for hospice care.

(b) *Content of certification.* Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:

(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(2) Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

(3) The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms.

(i) If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature.

(ii) If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.

(iii) The narrative shall include a statement directly above the physician signature attesting that by signing,

the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient.

(iv) The narrative must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients.

(v) The narrative associated with the 3rd benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less.

(4) The physician or nurse practitioner who performs the face-to-face encounter with the patient described in paragraph (a)(4) of this section must attest in writing that he or she had a face-to-face encounter with the patient, including the date of that visit. The attestation of the nurse practitioner or a non-certifying hospice physician shall state that the clinical findings of that visit were provided to the certifying physician for use in determining continued eligibility for hospice care.

(5) All certifications and recertifications must be signed and dated by the physician(s), and must include the benefit period dates to which the certification or recertification applies.

(c) *Sources of certification.* (1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from—

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician, if the individual has an attending physician. The attending physician must meet the definition of physician specified in § 410.20 of this subchapter.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) *Maintenance of records.* Hospice staff must—

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 45144, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005; 74 FR 39413, Aug. 6, 2009; 75 FR 70463, Nov. 17, 2010; 76 FR 47331, Aug. 4, 2011]

§ 418.24 Election of hospice care.

(a) *Filing an election statement.* An individual who meets the eligibility requirement of § 418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in § 418.3) may file the election statement.

(b) *Content of election statement.* The election statement must include the following:

(1) Identification of the particular hospice that will provide care to the individual.

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in paragraph (d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

(c) *Duration of election.* An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice;

(2) Does not revoke the election; and

(3) Is not discharged from the hospice under the provisions of § 418.26.

(d) *Waiver of other benefits.* For the duration of an election of hospice care, an individual waives all rights to Medicare payments for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under

arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice:

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(e) *Re-election of hospice benefits.* If an election has been revoked in accordance with § 418.28, the individual (or his or her representative if the individual is mentally or physically incapacitated) may at any time file an election, in accordance with this section, for any other election period that is still available to the individual.

[55 FR 50834, Dec. 11, 1990, as amended at 70 FR 70547, Nov. 22, 2005]

§ 418.25 Admission to hospice care.

(a) The hospice admits a patient only on the recommendation of the medical director in consultation with, or with input from, the patient's attending physician (if any).

(b) In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:

(1) Diagnosis of the terminal condition of the patient.

(2) Other health conditions, whether related or unrelated to the terminal condition.

(3) Current clinically relevant information supporting all diagnoses.

[70 FR 70547, Nov. 22, 2005]

§ 418.26 Discharge from hospice care.

(a) *Reasons for discharge.* A hospice may discharge a patient if—

(1) The patient moves out of the hospice's service area or transfers to another hospice;

(2) The hospice determines that the patient is no longer terminally ill; or

(3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(i) through (a)(3)(iv) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice must do the following before it seeks to discharge a patient for cause:

(i) Advise the patient that a discharge for cause is being considered;

(ii) Make a serious effort to resolve the problem(s) presented by the patient's behavior or situation;

(iii) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and

(iv) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(b) *Discharge order.* Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

(c) *Effect of discharge.* An individual, upon discharge from the hospice during a particular election period for reasons other than immediate transfer to another hospice—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(d); and

(3) May at any time elect to receive hospice care if he or she is again eligible to receive the benefit.

(d) *Discharge planning.* (1) The hospice must have in place a discharge planning process that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill.

(2) The discharge planning process must include planning for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

[70 FR 70547, Nov. 22, 2005]

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

§ 418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

Subpart C—Conditions of Participation: Patient Care

SOURCE: 73 FR 32204, June 5, 2008, unless other noted.

§ 418.52 Condition of participation: Patient's rights.

The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights and responsibilities.* (1) During the initial assessment visit in advance of furnishing care the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands.

(2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law.

(3) The hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right:

(i) To exercise his or her rights as a patient of the hospice;

(ii) To have his or her property and person treated with respect;

(iii) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and

(iv) To not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a patient has been adjudged incompetent under state law by a court

of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to state law to act on the patient's behalf.

(3) If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

(4) The hospice must:

(i) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(ii) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures;

(iii) Take appropriate corrective action in accordance with state law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

(iv) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

(c) *Standard: Rights of the patient.* The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

(2) Be involved in developing his or her hospice plan of care;

(3) Refuse care or treatment;

(4) Choose his or her attending physician;

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

(7) Receive information about the services covered under the hospice benefit;

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

§ 418.54 Condition of participation: Initial and comprehensive assessment of the patient.

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(a) *Standard: Initial assessment.* The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with § 418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(b) *Standard: Timeframe for completion of the comprehensive assessment.* The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with § 418.24.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints).

(2) Complications and risk factors that affect care planning.

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

(4) Imminence of death.

(5) Severity of symptoms.

(6) *Drug profile.* A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) Effectiveness of drug therapy.

(ii) Drug side effects.

(iii) Actual or potential drug interactions.

(iv) Duplicate drug therapy.

(v) Drug therapy currently associated with laboratory monitoring.

(7) *Bereavement.* An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.

(8) The need for referrals and further evaluation by appropriate health professionals.

(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

(2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

(a) *Standard: Approach to service delivery.* (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group, in its entirety, must supervise the care and services. The hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice).

(ii) A registered nurse.
(iii) A social worker.
(iv) A pastoral or other counselor.
(2) If the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.

(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire. The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

(c) *Standard: Content of the plan of care.* The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the following:

(1) Interventions to manage pain and symptoms.

(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs.

(3) Measurable outcomes anticipated from implementing and coordinating the plan of care.

(4) Drugs and treatment necessary to meet the needs of the patient.

(5) Medical supplies and appliances necessary to meet the needs of the patient.

(6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

(d) *Standard: Review of the plan of care.* The hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) must review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and must note the patient's progress toward outcomes and goals specified in the plan of care.

(e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to—

(1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that the care and services are provided in accordance with the plan of care.

(3) Ensure that the care and services provided are based on all assessments of the patient and family needs.

(4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.

(5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

§ 418.58 Condition of participation: Quality assessment and performance improvement.

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence

of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

(2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.

(2) The hospice must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the hospice's governing body.

(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect palliative outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

(3) The hospice must take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* Beginning February 2, 2009 hospices must develop, implement, and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

(2) The hospice must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually.

(2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

§ 418.60 Condition of participation: Infection control.

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.

(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that—

(1) Is an integral part of the hospice's quality assessment and performance improvement program; and

(2) Includes the following:

(i) A method of identifying infectious and communicable disease problems; and

(ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

§ 418.62 Condition of participation: Licensed professional services.

(a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under § 418.114 and who practice under the hospice's policies and procedures.

(b) Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

(c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

CORE SERVICES

§ 418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in paragraph (a) of this section. A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness.

(1) All physician employees and those under contract, must function under the supervision of the hospice medical director.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial assessment, comprehensive assessment, and updated assessments.

(2) If State law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and

the patient's and family's needs and acceptance of these services.

(d) *Standard: Counseling services.* Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. Counseling services must include, but are not limited to, the following:

(1) *Bereavement counseling.* The hospice must:

(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling.

(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/IID when appropriate and identified in the bereavement plan of care.

(iii) Ensure that bereavement services reflect the needs of the bereaved.

(iv) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c).

(2) *Dietary counseling.* Dietary counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

(3) *Spiritual counseling.* The hospice must:

(i) Provide an assessment of the patient's and family's spiritual needs.

(ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires.

(iii) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

(iv) Advise the patient and family of this service.

§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria:

(1) The location of the hospice's central office is in a non-urbanized area as determined by the Bureau of the Census.

(2) There is evidence that a hospice was operational on or before January 1, 1983 including the following:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983.

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.

(iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Job descriptions for nurse employees.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.

NON-CORE SERVICES

§ 418.70 Condition of participation: Furnishing of non-core services.

A hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by the hospice or under arrangements made by the hospice as specified in § 418.100. These services must be provided in a manner consistent with current standards of practice.

§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§ 418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

(a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria:

(1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census.

(2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include the following:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) An initial waiver will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

§ 418.76 Condition of participation: Hospice aide and homemaker services.

All hospice aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) *Standard: Hospice aide qualifications.* (1) A qualified hospice aide is a person who has successfully completed one of the following:

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.

(2) A hospice aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Content and duration of hospice aide classroom and supervised practical training.* (1) Hospice aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse, or a licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A hospice aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist:

(A) Bed bath.

(B) Sponge, tub, and shower bath.

(C) Hair shampoo (sink, tub, and bed).

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training hospice aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.

(c) *Standard: Competency evaluation.* An individual may furnish hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be

evaluated through written examination, oral examination, or after observation of a hospice aide with a patient.

(2) A hospice aide competency evaluation program may be offered by any organization, except as described in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A hospice aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) *Standard: In-service training.* A hospice aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization, and must be supervised by a registered nurse.

(2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

(f) *Standard: Eligible competency evaluation organizations.* A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

(1) Had been out of compliance with the requirements of §484.36(a) and §484.36 (b) of this chapter.

(2) Permitted an individual that does not meet the definition of a ''qualified home health aide'' as specified in §484.36(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).

(3) Had been subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State).

(4) Had been assessed a civil monetary penalty of $5,000 or more as an intermediate sanction.

(5) Had been found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency.

(6) Had all or part of its Medicare payments suspended.

(7) Had been found by CMS or the State under any Federal or State law to have:

(i) Had its participation in the Medicare program terminated.

(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies.

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled.

(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients.

(v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) *Standard: Hospice aide assignments and duties.* (1) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

(2) A hospice aide provides services that are:

(i) Ordered by the interdisciplinary group.

(ii) Included in the plan of care.

(iii) Permitted to be performed under State law by such hospice aide.

(iv) Consistent with the hospice aide training.

(3) The duties of a hospice aide include the following:

(i) The provision of hands-on personal care.

(ii) The performance of simple procedures as an extension of therapy or nursing services.

(iii) Assistance in ambulation or exercises.

(iv) Assistance in administering medications that are ordinarily self-administered.

(4) Hospice aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse, as the changes relate to the plan of care and quality assessment and improvement activities. Hospice aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) *Standard: Supervision of hospice aides.* (1) A registered nurse must make an on-site visit to the patient's home:

(i) No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

(ii) If an area of concern is noted by the supervising nurse, then the hospice must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete a competency evaluation in accordance with §418.76(c).

(2) A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(3) The supervising nurse must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to—

(i) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse.

(ii) Creating successful interpersonal relationships with the patient and family.

(iii) Demonstrating competency with assigned tasks.

(iv) Complying with infection control policies and procedures.

(v) Reporting changes in the patient's condition.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of a hospice agency.

(1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.

(2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.

(3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

(j) *Standard: Homemaker qualifications.* A qualified homemaker is—

(1) An individual who meets the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or

(2) A hospice aide as described in §418.76.

(k) *Standard: Homemaker supervision and duties.* (1) Homemaker services must be coordinated and supervised by

a member of the interdisciplinary group.

(2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group.

(3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009]

§ 418.78 Conditions of participation—Volunteers.

The hospice must use volunteers to the extent specified in paragraph (e) of this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.

(a) *Standard: Training*. The hospice must maintain, document, and provide volunteer orientation and training that is consistent with hospice industry standards.

(b) *Standard: Role*. Volunteers must be used in day-to-day administrative and/or direct patient care roles.

(c) *Standard: Recruiting and retaining*. The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving*. The hospice must document the cost savings achieved through the use of volunteers. Documentation must include the following:

(1) The identification of each position that is occupied by a volunteer.

(2) The work time spent by volunteers occupying those positions.

(3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.

(e) *Standard: Level of activity*. Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked.

Subpart D—Conditions of participation: Organizational Environment

SOURCE: 73 FR 32204, June 5, 2008, unless otherwise noted.

§ 418.100 Condition of Participation: Organization and administration of services.

The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Serving the hospice patient and family*. The hospice must provide hospice care that—

(1) Optimizes comfort and dignity; and

(2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

(b) *Standard: Governing body and administrator*. A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator appointed by and reporting to the governing body is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.

(c) *Standard: Services*. (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent with accepted standards of practice:

(i) Nursing services.

(ii) Medical social services.

(iii) Physician services.

(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.

(v) Hospice aide, volunteer, and homemaker services.

(vi) Physical therapy, occupational therapy, and speech-language pathology services.

(vii) Short-term inpatient care.

(viii) Medical supplies (including drugs and biologicals) and medical appliances.

(2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(d) *Standard: Continuation of care.* A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

(e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—

(1) Authorized by the hospice;

(2) Furnished in a safe and effective manner by qualified personnel; and

(3) Delivered in accordance with the patient's plan of care.

(f) *Standard: Hospice multiple locations.* If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

(i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.

(ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.

(iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location which was issued the certification number.

(iv) The determination that a multiple location does or does not meet the definition of a multiple location, as set forth in this part, is an initial determination, as set forth in § 498.3.

(2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care, in accordance with the requirements of this subpart and subparts A and C of this section.

(g) *Standard: Training.* (1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

(2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.

(3) A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009]

§ 418.102 Condition of participation: Medical director.

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is an employee, or is under contract with the hospice. When the medical director is not available, a physician designated by the hospice assumes the same responsibilities and obligations as the medical director.

(a) *Standard: Medical director contract.* (1) A hospice may contract with either of the following—

(i) A self-employed physician; or

(ii) A physician employed by a professional entity or physicians group. When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

(b) *Standard: Initial certification of terminal illness.* The medical director or physician designee reviews the clinical

information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following when making this determination:

(1) The primary terminal condition;

(2) Related diagnosis(es), if any;

(3) Current subjective and objective medical findings;

(4) Current medication and treatment orders; and

(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) *Standard: Recertification of the termina terminal illness*. Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review the patient's clinical information.

(d) *Standard: Medical director responsibility*. The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

§418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) *Standard: Content*. Each patient's record must include the following:

(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.

(2) Signed copies of the notice of patient rights in accordance with §418.52 and election statement in accordance with §418.24.

(3) Responses to medications, symptom management, treatments, and services.

(4) Outcome measure data elements, as described in §418.54(e) of this subpart.

(5) Physician certification and recertification of terminal illness as required in §§418.22 and 418.25 and described in §§418.102(b) and 418.102(c) respectively, if appropriate.

(6) Any advance directives as described in §418.52(a)(2).

(7) Physician orders.

(b) *Standard: Authentication*. All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

(c) *Standard: Protection of information*. The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

(d) *Standard: Retention of records*. Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) *Standard: Discharge or transfer of care*. (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient's attending physician, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e)(1) and (e)(2) of this section must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management.

(ii) The patient's current plan of care.

(iii) The patient's latest physician orders. and

(iv) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving facility.

(f) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) *Standard: Managing drugs and biologicals.* (1) The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

(2) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(b) *Standard: Ordering of drugs.* (1) Only a physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, may order drugs for the patient.

(2) If the drug order is verbal or given by or through electronic transmission—

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

(c) *Standard: Dispensing of drugs and biologicals.* The hospice must—

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

(d) *Standard: Administration of drugs and biologicals.* (1) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home.

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;

(ii) An employee who has completed a State-approved training program in medication administration; and

(iii) The patient, upon approval by the interdisciplinary group.

(e) *Standard: Labeling, disposing, and storing of drugs and biologicals*—(1) *Labeling.* Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) *Disposing.* (i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the

time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) *Storing.* The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements—

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

(f) *Standard: Use and maintenance of equipment and supplies.* (1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR 424.57.

§418.108 Condition of participation: Short-term inpatient care.

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in §418.110.

(2) A Medicare-certified hospital or a skilled nursing facility that also meets the standards specified in §418.110(b) and (e) regarding 24-hour nursing services and patient areas.

(b) *Standard: Inpatient care for respite purposes.* (1) Inpatient care for respite

purposes must be provided by one of the following:

(i) A provider specified in paragraph (a) of this section.

(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in § 418.110(e).

(2) The facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies—

(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented; and

(6) A method for verifying that the requirements in paragraphs (c)(1) through (c)(5) of this section are met.

(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month period in a particular hospice may not exceed 20 percent of the total number of hospice days consumed in total by this group of beneficiaries.

(e) *Standard: Exemption from limitation.* Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.

[73 FR 32204, June 5, 2008, as amended at 74 FR 39413, Aug. 6, 2009]

§ 418.110 Condition of participation: Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

(a) *Standard: Staffing.* The hospice is responsible for ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) *Standard: Twenty-four hour nursing services.* (1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) *Safety management.* (i) The hospice must address real or potential threats to the health and safety of the patients, others, and property.

(ii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(2) *Physical plant and equipment.* The hospice must develop procedures for controlling the reliability and quality of—

(i) The routine storage and prompt disposal of trash and medical waste;

(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and

(iv) The scheduled and emergency maintenance and repair of all equipment.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospices.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/codeoffederal__regulations/*

ibr__locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the FEDERAL REGISTER to announce the changes.

(e) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(f) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

(i) Be at or above grade level;

(ii) Contain a suitable bed and other appropriate furniture for each patient;

(iii) Have closet space that provides security and privacy for clothing and personal belongings;

(iv) Accommodate no more than two patients and their family members;

(v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and

(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and

(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(g) *Standard: Toilet and bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(h) *Standard: Plumbing facilities.* The hospice must—

(1) Have an adequate supply of hot water at all times; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(i) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in § 418.60.

(j) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(k) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(l) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are—

(1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;

(2) Palatable, attractive, and served at the proper temperature; and

(3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(m) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to

ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(3) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(7) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospice policy.

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(9) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have completed the training criteria specified in paragraph (n) of this section at an interval determined by hospice policy.

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

(13) If the face-to-face evaluation specified in §418.110(m)(11) is conducted by a trained registered nurse, the trained registered nurse must consult

the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(15) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(n) *Standard: Restraint or seclusion staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospice policy.

(2) *Training content.* The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(o) *Standard: Death reporting requirements.* Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.

(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

§418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/IID must abide by the following additional standards.

(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/IID are subject to the Medicare hospice eligibility criteria set out at §418.20 through §418.30.

(b) *Standard: Professional management.* The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §§418.100 and 418.108.

(c) *Standard: Written agreement.* The hospice and SNF/NF or ICF/IID must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/IID before the provision of hospice services. The written agreement must include at least the following:

(1) The manner in which the SNF/NF or ICF/IID and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.

(2) A provision that the SNF/NF or ICF/IID immediately notifies the hospice if—

(i) A significant change in a patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

(iii) A need to transfer a patient from the SNF/NF or ICF/IID, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related conditions; or

(iv) A patient dies.

(3) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

(4) An agreement that it is the SNF/NF or ICF/IID responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

(5) An agreement that it is the hospice's responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/IID resident were in his or her own home.

(6) A delineation of the hospice's responsibilities, which include, but are not limited to the following: Providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

(7) A provision that the hospice may use the SNF/NF or ICF/IID nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/IID to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/IID administrator within 24 hours of the hospice becoming aware of the alleged violation.

(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/IID to provide bereavement services to SNF/NF or ICF/IID staff.

(d) *Standard: Hospice plan of care.* In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/IID representatives. All hospice care provided must be in accordance with this hospice plan of care.

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/IID, and the patient and family to the extent possible.

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/IID representatives, and must be approved by the hospice before implementation.

(e) *Standard: Coordination of services.* The hospice must:

(1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/IID. The designated interdisciplinary group member is responsible for:

(i) Providing overall coordination of the hospice care of the SNF/NF or ICF/IID resident with SNF/NF or ICF/IID representatives; and

(ii) Communicating with SNF/NF or ICF/IID representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/IID medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

(3) Provide the SNF/NF or ICF/IID with the following information:

(i) The most recent hospice plan of care specific to each patient;

(ii) Hospice election form and any advance directives specific to each patient;

(iii) Physician certification and recertification of the terminal illness specific to each patient;

(iv) Names and contact information for hospice personnel involved in hospice care of each patient;

(v) Instructions on how to access the hospice's 24-hour on-call system;

(vi) Hospice medication information specific to each patient; and

(vii) Hospice physician and attending physician (if any) orders specific to each patient.

(f) *Standard: Orientation and training of staff.* Hospice staff must assure orientation of SNF/NF or ICF/IID staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

§418.114 Condition of participation: Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements

with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

(b) *Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Physician.* Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

(2) *Hospice aide.* Hospice aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at §418.76.

(3) *Social worker.* A person who—

(i)(A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and

(ii) Has 1 year of social work experience in a healthcare setting; or

(iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before December 2, 2008, and is not required to be supervised by an MSW.

(4) *Speech language pathologist.* A person who meets either of the following requirements:

(i) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(5) *Occupational therapist.* A person who—

(i)(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(B) When licensure or other regulation does not apply—

(*1*) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(*2*) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(iii) On or before January 1, 2008—

(A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapist; and

(B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States—

(A) Must meet both of the following:

(*1*) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(*i*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*ii*) Successor organizations of ACOTE.

(*iii*) The World Federation of Occupational Therapists.

(*iv*) A credentialing body approved by the American Occupational Therapy Association.

(*v*) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(*2*) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

(6) *Occupational therapy assistant.* A person who

(i) Meets all of the following:

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.

(B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(*1*) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(*2*) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(*1*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*2*) Its successor organizations.

(*3*) The World Federation of Occupational Therapists.

(*4*) By a credentialing body approved by the American Occupational Therapy Association; and

(*5*) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(7) *Physical therapist.* A person who is licensed, if applicable, by the State in which practicing, unless licensure does

not apply and meets one of the following requirements:

(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(D) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(ii) On or before December 31, 2009—

(A) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(B) Meets both of the following:

(*1*) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(*2*) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(iii) Before January 1, 2008—

(A) Graduated from a physical therapy curriculum approved by one of the following:

(*1*) The American Physical Therapy Association.

(*2*) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(*3*) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(A) Has 2 years of appropriate experience as a physical therapist.

(B) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) Before January 1, 1966—

(A) Was admitted to membership by the American Physical Therapy Association;

(B) Was admitted to registration by the American Registry of Physical Therapists; and

(C) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(vii) If trained outside the United States before January 1, 2008, meets the following requirements:

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(8) *Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education

program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(A) On or before December 31, 2009, meets one of the following:

(*1*) Is licensed, or otherwise regulated in the State in which practicing.

(*2*) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

(*3*) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(*4*) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.* If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

(1) *Registered nurse.* A graduate of a school of professional nursing.

(2) *Licensed practical nurse.* A person who has completed a practical nursing program.

(d) *Standard: Criminal background checks.* (1) The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.

(a) *Standard: Multiple locations.* Every hospice must comply with the requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(b) *Standard: Laboratory services.* (1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Subpart E [Reserved]

Subpart F—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation and management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with § 418.24. A plan of care must be established and

periodically reviewed by the attending physician, the medical director, and the interdisciplinary group of the hospice program as set forth in § 418.56. That plan of care must be established before hospice care is provided. The services provided must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in section § 418.22.

[74 FR 39413, Aug. 6, 2009]

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in § 410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in § 418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in § 418.108(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) *Medical appliances and supplies, including drugs and biologicals.* Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care and that are for palliation and management of the terminal or related conditions.

(g) *Home health or hospice aide services furnished by qualified aides as designated in § 418.76 and homemaker services.* Home health aides (also known as hospice aides) may provide personal care services as defined in § 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

(i) Effective April 1, 1998, any other service that is specified in the patient's

plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994; 70 FR 70547, Nov. 22, 2005; 73 FR 32220, June 5, 2008; 74 FR 39413, Aug. 6, 2009; 76 FR 47331, Aug. 4, 2011]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide (also known as hospice aide) services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation and management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990; 74 FR 39413, Aug. 6, 2009]

§ 418.205 Special requirements for hospice pre-election evaluation and counseling services.

(a) *Definition.* As used in this section the following definition applies.

Terminal illness has the same meaning as defined in § 418.3.

(b) *General.* Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in § 418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) *The beneficiary.* The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in § 418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) *Services provided.* The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling regarding hospice and other care options. In addition, the services may include advising the individual regarding advanced care planning.

(3) *Provision of pre-election hospice services.* (i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) *Documentation.* (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the

services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

[69 FR 66425, Nov. 15, 2004]

Subpart G—Payment for Hospice Care

§418.301 Basic rules.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in §418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in §418.309.

(c) The hospice may not charge a patient for services for which the patient is entitled to have payment made under Medicare or for services for which the patient would be entitled to payment, as described in §489.21 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 70547, Nov. 22, 2005]

§418.302 Payment procedures for hospice care.

(a) CMS establishes payment amounts for specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide (also known as a hospice aide) or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in §418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are established by CMS in accordance with the procedures described in §418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d)(1) The intermediary reimburses the hospice its appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(2) Effective December 8, 2003, if a hospice makes arrangements with another hospice to provide services under the circumstances specified in section 1861(dd)(5)(D) of the Act, the intermediary reimburses the hospice for which the beneficiary has made an election as described in paragraph (d)(1) of this section.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in §418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows:

(1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients. Only inpatient days that were provided and billed as general inpatient or respite days are counted as inpatient days when computing the inpatient cap.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in § 418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in § 418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

(g) Payment for routine home care, continuous home care, general inpatient care and inpatient respite care is made on the basis of the geographic location where the services are provided.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005; 72 FR 50228, Aug. 31, 2007; 74 FR 39414, Aug. 6, 2009]

§ 418.304 Payment for physician and nurse practitioner services.

(a) The following services performed by hospice physicians and nurse practitioners are included in the rates described in § 418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of

care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician fee schedule for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in §418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in §418.309. These services are paid by the carrier under the procedures in subpart B, part 414 of this chapter.

(d) *Payment for hospice pre-election evaluation and counseling services.* The intermediary makes payment to the hospice for the services established in §418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

(e)(1) Effective December 8, 2003, Medicare pays for attending physician services provided by nurse practitioners to Medicare beneficiaries who have elected the hospice benefit and who have selected a nurse practitioner as their attending physician. This applies to nurse practitioners without regard to whether they are hospice employees.

(2) Nurse practitioners may bill and receive payment for services only if the—

(i) Nurse practitioner is the beneficiary's attending physician as defined in §418.3;

(ii) Services are medically reasonable and necessary;

(iii) Services are performed by a physician in the absence of the nurse practitioner; and

(iv) Services are not related to the certification of terminal illness specified in §418.22.

(3) Payment for nurse practitioner services are made at 85 percent of the physician fee schedule amount.

[48 FR 56026, Dec. 16, 1983, as amended at 69 FR 66426, Nov. 15, 2004; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005]

§418.306 Determination of payment rates.

(a) *Applicability.* CMS establishes payment rates for each of the categories of hospice care described in §418.302(b). The rates are established using the methodology described in section 1814(i)(1)(C) of the Act.

(b) *Payment rates.* The payment rates for routine home care and other services included in hospice care are as follows:

(1) The following rates, which are 120 percent of the rates in effect on September 30, 1989, are effective January 1, 1990 through September 30, 1990 and October 21, 1990 through December 31, 1990:

Routine home care	$75.80
Continuous home care:	
Full rate for 24 hours	442.40
Hourly rate	18.43
Inpatient respite care	78.40
General inpatient care	337.20

(2) Except for the period beginning October 21, 1990, through December 31, 1990, the payment rates for routine home care and other services included in hospice care for Federal fiscal years 1991, 1992, and 1993 and those that begin on or after October 1, 1997, are the payment rates in effect under this paragraph during the previous fiscal year increased by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act, otherwise applicable to discharges occurring in the fiscal year. The payment rates for the period beginning October 21, 1990, through December 31, 1990, are the

same as those shown in paragraph (b)(1) of this section.

(3) For Federal fiscal years 1994 through 2002, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus—

(i) 2 percentage points in FY 1994;

(ii) 1.5 percentage points in FYs 1995 and 1996;

(iii) 0.5 percentage points in FY 1997; and

(iv) 1 percentage point in FY 1998 through FY 2002.

(4) For Federal fiscal year 2001, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase plus 5 percentage points. However, this payment rate is effective only for the period April 1, 2001 through September 30, 2001. For the period October 1, 2000 through March 31, 2001, the payment rate is based upon the rule under paragraph (b)(3)(iv) of this section. The payment rate in effect during the period April 1, 2001 through September 30, 2001 is considered the payment rate in effect during fiscal year 2001.

(5) The payment rate for hospice services furnished during fiscal years 2001 and 2002 is increased by an additional 0.5 percent and 0.75 percent, respectively. This additional amount is not included in updating the payment rate as described in paragraph (b)(3) of this section.

(c) *Adjustment for wage differences.* Each hospice's labor market is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by OMB. CMS will issue annually, in the FEDERAL REGISTER, a hospice wage index based on the most current available CMS hospital wage data, including changes to the definition of MSAs. The urban and rural area geographic classifications are defined in §412.64(b)(1)(ii)(A) through (C) of this chapter. The payment rates established by CMS are adjusted by the intermediary to reflect local differences in wages according to the revised wage data.

(d) *Federal Register notices.* CMS publishes as a notice in the FEDERAL REGISTER any proposal to change the methodology for determining the payment rates.

[56 FR 26919, June 12, 1991, as amended at 59 FR 26960, May 25, 1994; 62 FR 42882, Aug. 8, 1997; 70 FR 70548, Nov. 22, 2005; 73 FR 46486, Aug. 8, 2008]

§ 418.307 Periodic interim payments.

Subject to the provisions of §413.64(h) of this chapter, a hospice may elect to receive periodic interim payments (PIP) effective with claims received on or after July 1, 1987. Payment is made biweekly under the PIP method unless the hospice requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payments for the reporting period (as described in §§418.302–418.306). Each payment is made 2 weeks after the end of a biweekly period of service as described in §413.64(h)(5) of this chapter. Under certain circumstances that are described in §413.64(g) of this chapter, a hospice that is not receiving PIP may request an accelerated payment.

[59 FR 36713, July 19, 1994]

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in §418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in §418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in §405.1803 of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.309 Hospice aggregate cap.

A hospice's aggregate cap is calculated by multiplying the adjusted cap amount (determined in paragraph (a) of this section) by the number of Medicare beneficiaries, as determined by one of two methodologies for determining the number of Medicare beneficiaries for a given cap year described in paragraphs (b) and (c) of this section:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) *Streamlined methodology defined.* A hospice's aggregate cap is calculated by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries as determined in paragraphs (b)(1) and (2) of this section. For purposes of the streamlined methodology calculation—

(1) In the case in which a beneficiary received care from only one hospice, the hospice includes in its number of Medicare beneficiaries those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap, and who have filed an election to receive hospice care in accordance with § 418.24 during the period beginning on September 28 (34 days before the beginning of the cap year) and ending on September 27 (35 days before the end of the cap year), using the best data available at the time of the calculation.

(2) In the case in which a beneficiary received care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all hospices and all years that was spent in that hospice in that cap year, using the best data available at the time of the calculation. The aggregate cap calculation for a given cap year may be adjusted after the calculation for that year based on updated data.

(c) *Patient-by-patient proportional methodology defined.* A hospice's aggregate cap is calculated by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries as described in paragraphs (c)(1) and (2) of this section. For the purposes of the patient-by-patient proportional methodology—

(1) A hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all hospices and all years that was spent in that hospice in that cap year, using the best data available at the time of the calculation. The total number of Medicare beneficiaries for a given hospice's cap year is determined by summing the whole or fractional share of each Medicare beneficiary that received hospice care during the cap year, from that hospice.

(2) The aggregate cap calculation for a given cap year may be adjusted after the calculation for that year based on updated data.

(d) *Application of methodologies.* (1) For cap years ending October 31, 2011 and for prior cap years, a hospice's aggregate cap is calculated using the streamlined methodology described in paragraph (b) of this section, subject to the following:

(i) A hospice that has not received a cap determination for a cap year ending on or before October 31, 2011 as of October 1, 2011, may elect to have its final cap determination for such cap years calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section; or

(ii) A hospice that has filed a timely appeal regarding the methodology used for determining the number of Medicare beneficiaries in its cap calculation for any cap year is deemed to have elected that its cap determination for the challenged year, and all subsequent cap years, be calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section.

(2) For cap years ending October 31, 2012, and all subsequent cap years, a hospice's aggregate cap is calculated using the patient-by-patient proportional methodology described in paragraph (c) of this section, subject to the following:

(i) A hospice that has had its cap calculated using the patient-by-patient proportional methodology for any cap year(s) prior to the 2012 cap year is not eligible to elect the streamlined methodology, and must continue to have the patient-by-patient proportional methodology used to determine the number of Medicare beneficiaries in a given cap year.

(ii) A hospice that is eligible to make a one-time election to have its cap calculated using the streamlined methodology must make that election no later than 60 days after receipt of its 2012 cap determination. A hospice's election to have its cap calculated using the streamlined methodology would remain in effect unless:

(A) The hospice subsequently submits a written election to change the methodology used in its cap determination to the patient-by-patient proportional methodology; or

(B) The hospice appeals the streamlined methodology used to determine the number of Medicare beneficiaries used in the aggregate cap calculation.

(3) If a hospice that elected to have its aggregate cap calculated using the streamlined methodology under paragraph (d)(2)(ii) of this section subsequently elects the patient-by-patient proportional methodology or appeals the streamlined methodology, under paragraph (d)(2)(ii)(A) or (B) of this section, the hospice's aggregate cap determination for that cap year and all subsequent cap years is to be calculated using the patient-by-patient proportional methodology. As such, past cap year determinations may be adjusted to prevent the over-counting of beneficiaries, subject to existing reopening regulations.

[48 FR 56026, Dec. 16, 1983, as amended at 76 FR 47332, Aug. 4, 2011]

§ 418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§ 418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR part 405, subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under § 405.1874 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the statutorily defined payment rates by CMS are not subject to appeal.

[74 FR 39414, Aug. 6, 2009]

Subpart H—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with § 418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by CMS for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with §418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in §418.400, that are considered covered hospice care (as described in §418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by CMS in accordance with §418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, CMS offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

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AUTHORITY: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 419.1 Basis and scope.

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment.* Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Included costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to—

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and

(12) Costs incurred to procure donor tissue other than corneal tissue.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.*

The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in §§ 413.75 through 413.83 of this chapter.

(2) The costs of nursing and allied health programs as described in § 413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in § 415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under § 415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in § 413.89(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition costs.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 70 FR 47490, Aug. 12, 2005]

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001]

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a home health agency (HHA) to patients who are not under an HHA plan or treatment or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Hepatitis B vaccine.

(e)(1) Effective January 1, 2005 through December 31, 2008, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 6 months after the individual's initial Part B coverage date that begins on or after January 1, 2005.

(2) Effective January 1, 2009, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 12 months after the date of the individual's initial enrollment in Part B.

[65 FR 18542, Apr. 7, 2000, as amended at 67 FR 66813, Nov. 1, 2002; 69 FR 65863, Nov. 15, 2004; 71 FR 68227, Nov. 24, 2006: 75 FR 72265, Nov. 24, 2010]

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Clinical diagnostic laboratory services.

(m)(1) Services provided on or before December 31, 2010, for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(2) Renal dialysis services provided on or after January 1, 2011, for patients with ESRD that are paid under the ESRD benefit, as described in subpart H of part 413 of this chapter.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital ''under arrangements'' but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

(s) Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.

(t) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 69 FR 65863, Nov. 15, 2004; 75 FR 72265, Nov. 24, 2010]

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) CMS estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) CMS may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the median costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) CMS determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the ''labor-related portion'' of hospital outpatient costs.

(2) CMS standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* CMS calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001—

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional

percentage allowance equal to 0.32 percent.

(iii) For the portion of calendar year 2002 that is affected by these rules, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in § 419.32(b)(ii)(B).

(iv)(A) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, reduced by the factor(s) specified in paragraph (b)(1)(iv)(B) of this section.

(B) The percentage increase determined under paragraph (b)(1)(iv)(A) of this section is reduced by the following for the specific calendar year:

(*1*) For calendar year 2010, 0.25 percentage point;

(*2*) For calendar year 2011, 0.25 percentage point; and

(*3*) For calendar year 2012, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) *Budget neutrality.* (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 67 FR 9568, Mar. 1, 2002; 69 FR 832, Jan. 6, 2004; 75 FR 72265, Nov. 24, 2010; 77 FR 74582, Nov. 30, 2011]

EFFECTIVE DATE NOTE: At 66 FR 59922, Nov. 30, 2001, § 41932 was amended by revising paragraph (b)(1), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, paragraph (b)(1)(iii) was delayed indefinitely.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary copayment amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount.* The copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

[66 FR 59922, Nov. 30, 2001]

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted copayment amount for each APC group, CMS—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary copayment amount for the APC group.

(b) CMS calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted copayment amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, CMS makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the copayment amount.

(i) The copayment amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the copayment amount for multiple APCs for a single drug or biological furnished on the same day will be aggregated and treated as the copayment amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the copayment amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the copayment amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the copayment amount for one APC.

(ii) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(iii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years 2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

(iv) The copayment amount is computed as if the adjustment under §§ 419.43(d) and (e) (and any adjustments made under § 419.43(f) in relation to these adjustments) and § 419.43(h) had not been paid.

(5) Adds the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined under § 419.32 or, in the case of payments calculated under § 419.43(h), not less than 20 percent of the APC payment rate as determined under § 419.43(h).

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 73 FR 68814, Nov. 18, 2008]

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

(a) *General rule.* CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the ''labor-related portion'' of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.*—(1) CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.

(2) For services furnished beginning January 1, 2011, the wage index factor provided for in paragraph (c)(1) of this section applicable to any hospital outpatient department that is located in a frontier State, as defined in § 412.64(m) of this chapter, may not be less than 1.00.

(3) The additional payments made under the provisions of paragraph (c)(2) of this section are not implemented in a budget neutral manner.

(d) *Outlier adjustment*—(1) *General rule.* Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under § 419.66.

(ii) At the option of CMS, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments*—(i) *In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments

(sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term ''applicable percentage'' means a percentage specified by CMS up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional passthrough payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(5) *Cost-to-charge ratios for calculating charges adjusted to cost.* For hospital outpatient services (or groups of services) as defined in paragraph (d)(1) of this section performed on or after January 1, 2009—

(i) CMS may specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section. A hospital may also request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.

(ii) The overall ancillary cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(iii) The Medicare contractor may use a statewide average cost-to-charge ratio if it is unable to determine an accurate overall ancillary cost-to-charge ratio for a hospital in one of the following circumstances:

(A) A new hospital that has not yet submitted its first Medicare cost report. (For purposes of this paragraph, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(B) A hospital whose overall ancillary cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 419.50(a).

(C) Any other hospital for whom accurate data to calculate an overall ancillary cost-to-charge ratio are not available to the Medicare contractor.

(6) *Reconciliation.* For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009—

(i) Any reconciliation of outlier payments will be based on an overall ancillary cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the service is settled.

(ii) At the time of any reconciliation under paragraph (d)(6)(i) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by CMS, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

(e) *Budget neutrality.* CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section:

(1) Drugs and biologicals that are paid under a separate APC; and

(2) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(g) *Payment adjustment for certain rural hospitals*—(1) *General rule.* CMS provides for additional payment for covered hospital outpatient services not excluded under paragraph (g)(4) of this section, furnished on or after January 1, 2006, if the hospital—

(i) Is a sole community hospital under § 412.92 of this chapter or is an essential access community hospital under § 412.109 of this chapter; and

(ii) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under § 412.103 of this chapter.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (g)(1) of this section is determined by CMS and is based on the difference between costs incurred by hospitals that meet the criteria in paragraphs (g)(1)(i) and (g)(1)(ii) of this section and costs incurred by hospitals located in urban areas.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (g)(2) of this section in a budget neutral manner, excluding services and groups specified in paragraph (g)(4) of this section.

(4) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section:

(i) Drugs and biologicals that are paid under a separate APC;

(ii) Devices paid under 419.66; and

(iii) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(5) *Copayment.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating copayment amounts.

(6) *Outliers.* The payment adjustment in paragraph (g)(2) of this section is applied before calculating outlier payments.

(h) *Applicable adjustments to conversion factor for CY 2009 and for subsequent calendar years*—(1) *General rule.* For CY 2009 and for subsequent calendar years, the applicable adjustment to the conversion factor specified in § 419.32(b)(1)(iv) is reduced by 2.0 percentage points for any hospital that fails to meet the standards for reporting of hospital outpatient quality measures as established by the Secretary for the corresponding calendar year.

(2) *Limitation.* Any reduction to a hospital's adjustment to its conversion factor specified in § 419.32(b)(1)(iv) which occurs as a result of paragraph (h)(1) of this section will apply only to the calendar year involved and will not be taken into account in computing that hospital's applicable adjustment for a subsequent calendar year.

(3) *Budget neutrality.* For CY 2009 and for each subsequent calendar year, CMS makes an adjustment to the conversion factor, so that estimated aggregate payments under the OPPS for such calendar year are not affected by any reductions to hospital adjustments which occur as a result of paragraph (h)(1) of this section.

(4) *Beneficiary copayment.* The beneficiary copayment for services to which the adjustment to the conversion factor specified under paragraph (h)(1) of this section applies is the product of the national beneficiary copayment amount calculated under § 419.41 and the ratio of the adjusted conversion factor calculated under paragraph (h)(1) of this section divided by the conversion factor specified under § 419.32(b)(1).

(i) *Payment adjustment for certain cancer hospitals*—(1) *General rule.* CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) *Amount of payment adjustment.* The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable

CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to the amount needed to make the hospital's PCR at cost report settlement (as determined by the Secretary) equal to the target PCR (as determined by the Secretary).

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is greater than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to zero.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000; 66 FR 55856, Nov. 2, 2001; 69 FR 832, Jan. 6, 2004; 70 FR 68727, Nov. 10, 2005; 70 FR 76178, Dec. 23, 2005; 71 FR 68227, Nov. 24, 2006; 72 FR 66932, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011]

§ 419.44 Payment reductions for procedures.

(a) *Multiple surgical procedures.* When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Interrupted procedures.* When a procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full program and beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(2) One-half the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(3) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

[65 FR 18542, Apr. 7, 2000, as amended at 72 FR 66933, Nov. 27, 2007]

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for an implanted device made under the hospital outpatient prospective payment system in accordance with § 419.66 for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device, when one of the following situations occur:

(1) The device is replaced without cost to the provider or the beneficiary;

(2) The provider receives full credit for the cost of a replaced device; or

(3) The provider receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the APC payment.* (1) The amount of the reduction to the APC payment made under

paragraphs (a)(1) and (a)(2) of this section is calculated in the same manner as the offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is 50 percent of the offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66.

(c) *Amount of beneficiary copayment.* The beneficiary copayment is calculated based on the APC payment after application of the reduction under paragraph (b) of this section.

[71 FR 68228, Nov. 24, 2006, as amended at 72 FR 66933, Nov. 27, 2007]

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 55856, Nov. 2, 2001]

Subpart G—Transitional Pass-through Payments

SOURCE: 66 FR 55856, Nov. 2, 2001, unless otherwise noted.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the

total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For the portion of CY 2002 affected by these rules, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

[66 FR 55856, 55865, Nov. 2, 2001; 67 FR 9568, Mar. 1, 2002]

EFFECTIVE DATE NOTE: At 66 FR 55865, Nov. 2, 2001, § 419.62 was amended by adding paragraph (d), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, the amendment was delayed indefinitely.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(iii) A biological that is not surgically implanted or inserted into the body.

(iv) A biological that is surgically implanted or inserted into the body, for which pass-through payment as a biological is made on or before December 31, 2009.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug

or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

[65 FR 18542, Apr. 7, 2000, as amended at 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004; 74 FR 60680, Nov. 20, 2009]

§ 419.66 Transitional pass-through payments: Medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related

portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002; 70 FR 68728, Nov. 10, 2005; 74 FR 60680, Nov. 20, 2009]

Subpart H—Transitional Corridors

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted. Redesignated at 66 FR 55856, Nov. 2, 2001.

§ 419.70 Transitional adjustments to limit decline in payments.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part

is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals before January 1, 2006.* For covered hospital outpatient services furnished in a calendar year before January 1, 2006, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) Temporary treatment for small rural hospitals on or after January 1, 2006. For covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, and 2011 if the hospital—

(i) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter;

(iii) Is not a sole community hospital as defined in § 412.92 of this chapter; and

(iv) Is not an essential access community hospital under § 412.109 of this chapter.

(3) *Permanent treatment for cancer hospitals and children's hospitals.* In the case of a hospital described in § 412.23(d) or § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(4) *Temporary treatment for sole community hospitals located in rural areas for covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004 and before January 1, 2006.* For covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.63(b) or § 412.64(b), as applicable, of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act.

(5) *Temporary treatment for small sole community hospitals on or after January 1, 2009 and through December 31, 2009.* For covered hospital outpatient services furnished on or after January 1, 2009, and continuing through December 31, 2009, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(i) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(6) *Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011.* For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter.

(e) *Prospective payment system amount defined.* In this section, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this section or any reduction in coinsurance elected under §419.42), including amounts payable as copayment under §419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule.* In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, CMS shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services furnished during one of the following periods, including any payment for these services through cost-sharing described in paragraph (e) of this section:

(A) The cost reporting period ending in 1996; or

(B) If the provider does not have a cost reporting period ending in 1996, the first cost reporting period ending on or after January 1, 1997, and before January 1, 2001; and

(ii) The reasonable costs of these services for the same cost reporting period.

(g) *Interim payments.* CMS makes payments under this section to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in §419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this section—

(1) Are not considered an adjustment under §419.43(f); and

(2) Are not implemented in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004; 71 FR 68228, Nov. 24, 2006; 72 FR 66933, Nov. 27, 2007; 73 FR 68814, Nov. 18, 2008; 74 FR 60681, Nov. 20, 2009; 75 FR 72265, Nov. 24, 2010; 76 FR 74583, Nov. 30, 2011]

PART 420—PROGRAM INTEGRITY: MEDICARE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W–2 employee.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of $25,000 and 5 percent of the total operating expenses of the provider.

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992; 71 FR 20775, Apr. 21, 2006]

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest

owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. *Similar capacity* means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to CMS's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by CMS, the provider or part B supplier must furnish CMS with the identity of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* CMS may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, CMS considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. CMS also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* CMS promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to CMS, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

[57 FR 27306, June 18, 1992]

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to CMS before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to CMS at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.* (1) CMS does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) CMS terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

§ 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

Books, documents, and records means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

Common ownership means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

Contract for services means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is $10,000 or more within a 12-month period.

Control means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

Provider means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in § 413.17 of this chapter) of any of these providers.

Related to the subcontractor means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

Subcontractor means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is $10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(l)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is $10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth $10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(l)(I)(ii) of the

Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.

(6) HHS reserves the right to examine the originals of any requested contracts, books, documents, and records, if they exist.

(c) *Refusal by subcontractor to furnish access to records.* If CMS determines that the books, documents, and records are necessary for the reimbursement determination and the subcontractor refuses to make them available, HHS may initiate legal action against the subcontractor.

Subpart E—Rewards for Information Relating to Medicare Fraud and Abuse, and Establishment of a Program to Collect Suggestions for Improving Medicare Program Efficiency and to Reward Suggesters for Monetary Savings

SOURCE: 63 FR 31128, June 8, 1998, unless otherwise noted.

§ 420.400 Basis and scope.

This subpart implements sections 203(b) and (c) of Public Law 104–191, which require the establishment of programs to encourage individuals to report suspected cases of fraud and abuse and submit suggestions on methods to improve the efficiency of the Medicare program. Sections 203(b) and (c) of Public Law 104–191 also provide the authority for CMS to reward individuals for reporting fraud and abuse and for submitting suggestions that could improve the efficiency of the Medicare program. This subpart sets forth procedures for rewarding individuals.

[64 FR 66401, Nov. 26, 1999]

§ 420.405 Rewards for information relating to Medicare fraud and abuse.

(a) *General rule.* CMS pays a monetary reward for information that leads to the recovery of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, section 1128A, or section 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program. The determination of whether an individual meets the criteria for an award, and the amount of the award, is at the discretion of CMS. CMS pays rewards only if a reward is not otherwise provided for by law. When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the beneficiary as specified in paragraph (d) of this section.

(b) *Information eligible for reward.* (1) In order for an individual to be eligible to receive a reward, the information he or she supplied must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities.

(2) CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or its contractors, or the OIG, the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency.

(c) *Persons eligible to receive a reward—*(1) *General rule.* Any person (other than one excluded under paragraph (c)(2) of this section) is eligible to receive a reward under this section if the person submits the information in the manner set forth in paragraph (f) of this section.

(2) *Excluded individuals.* (i) An individual who was, or is an immediate family member of, an officer or employee of HHS or its contractors, the SSA, the OIG, a State Medicaid Agency, or the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency at the time he or she came into possession of, or divulged, information leading to a recovery of Medicare funds is not eligible to receive a reward under this section.

(ii) Any other Federal or State employee or contractor or an HHS grantee is not eligible for a reward under this section if the information submitted came to his or her knowledge in the course of his or her official duties.

(iii) An individual who illegally obtained the information he or she submitted is excluded from receiving a reward under this section.

(iv) An individual who participated in the sanctionable offense with respect to which payment would be made is excluded from receiving a reward under this section.

(d) *Notification of eligibility*—(1) *General rule.* After all Medicare funds have been recovered and CMS has determined a participant eligible to receive a reward under the provisions of this section, it notifies the informant of his or her eligibility, by mail, at the most recent address supplied by the individual. It is the individual's responsibility to ensure that the reward program has been notified of any change in his or her address or other relevant personal information (for example, change of name, phone number).

(2) *Special circumstances.* (i) If the individual has relocated to an unknown address, the individual or his or her legal representative may claim the reward by contacting CMS within 1 year from the date on which CMS first attempted to notify the individual about a reward. CMS does not consider the individual or his or her legal representative eligible for a reward more than 1 year after the date on which it first attempted to give notice. CMS does not pay interest on rewards that are not immediately claimed.

(ii) If the individual has become incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the individual or the individual's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to show his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first gave or attempted to give notice of the reward.

(e) *Amount and payment of reward.* (1) In determining whether it will pay a reward and, if so, the amount of the reward, CMS takes into account all relevant factors, including the significance of the information furnished in relation to the ultimate resolution of the case and the recovery of Medicare funds.

(2) The amount of a reward represents what CMS considers to be adequate compensation in the particular case, not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less.

(3) If more than one person is eligible to receive a reward in a particular case, CMS allocates the total reward amount (not to exceed 10 percent of the overpayments recovered in that case or $1,000, whichever is less) among the participants.

(4) CMS bases rewards only on recovered Medicare payments and not on amounts collected as penalties or fines.

(5) CMS makes payments as promptly as the circumstances of the case permit, but not until it has collected all Medicare overpayments, fines, and penalties.

(6) No person may make any offer or promise or otherwise bind CMS or HHS with respect to the payment of any reward under this section or the amount of the reward.

(f) *Submission of information.* (1) An individual may submit information on persons or entities engaging in, or that have engaged in, fraud and abuse against the Medicare program to the Office of the Inspector General, or to the Medicare intermediary or carrier that has jurisdiction over the suspected fraudulent provider or supplier.

(2) A participant interested in receiving a reward must provide his or her name, address, telephone number, and any other requested identifying information so that he or she may be contacted, if necessary, for additional information and, when applicable, for the payment of a reward upon resolution of the case.

(g) *Confidentiality.* CMS does not reveal a participant's identity to any person, except as required by law.

(h) *Finding of ineligibility after reward is accepted.* If, after a reward is accepted, CMS finds that the awardee was ineligible to receive the reward, the Government is not liable for the reward

and the awardee must refund all monies received.

§ 420.410 Establishment of a program to collect suggestions for improving Medicare program efficiency and to reward suggesters for monetary savings.

(a) *Definitions.* As used in this section, the following definitions apply:

Payment means a monetary award given to a suggester in recognition of, and as a reward for, a suggestion adopted by CMS that improves the efficiency of, and results in monetary savings to, the Medicare program.

Savings means the monetary value of the net benefits the Medicare program derives from implementing the suggestion.

Suggester means an individual, a group of individuals, or a legal entity such as a corporation, partnership, or professional association, not otherwise excluded under § 420.410(d), who submits a suggestion under this section.

Suggestion means an original idea submitted in writing.

Suggestion program means the specific procedures and requirements established by CMS for receiving suggestions from the suggester on methods to improve the efficiency of the Medicare program, evaluating the suggestions and, if appropriate, paying a reward to the suggester for adopted suggestions that result in improved efficiency and produce monetary savings to the Medicare program.

(b) *General rule.* CMS may make payment for adopted suggestions that increase the efficiency of the Medicare program and result in monetary savings. CMS only makes payment for suggestions in instances in which a reward is not otherwise provided by law. The determination to adopt a suggestion, to reward the suggester, and the method of calculating a reward are at the sole discretion of CMS.

(c) *Eligibility.* Except as specified in paragraph (d) of this section, any individual, group of individuals or legal entity, such as a corporation, partnership or professional association, is eligible to submit a suggestion and be considered for a reward under this suggestion program if the suggestion is submitted to CMS in the manner set forth in paragraph (e) of this section.

(d) *Exclusions.* Medicare contractors, their officers and employees, individuals who work for Federal agencies under a contract, employees of Federally-sponsored research and demonstration projects, Federal officers and employees, and immediate family members of these individuals, are excluded from receiving payment under the suggestion program. If, after the suggester receives a reward payment, CMS determines that the suggester was ineligible to receive the reward, CMS is not liable for the reward payment and the suggester must refund all monies received.

(e) *Requirements for submitting suggestions*—(1) To be considered, the suggestion must be in writing, mailed to CMS, and must include the following information:

(i) A description of an existing problem or need;

(ii) A suggested method for solving the problem or filling the need; and

(iii) If known, an estimate of the savings potential that could result from implementing the suggestion.

(2) Suggestions must be mailed to: Centers for Medicare & Medicaid Services Suggestion Program, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

(3) Any suggesters interested in receiving a reward must provide CMS with the following information: An individual suggester must provide his or her name, a group of suggesters must provide the names of all the group members, and a legal entity must provide its name and the name of its representative. All suggesters must provide an address, telephone number, and any other identifying information that CMS needs to contact the suggester for additional information and, where applicable, to mail the reward.

(f) *Evaluation process*—(1) *Relevant factors.* CMS evaluates all suggestions on the basis of the following factors:

(i) Originality of suggestion.

(ii) An estimate of potential monetary savings to the Medicare program.

(iii) The extent to which Medicare program efficiency would be improved if CMS adopts the suggestion.

(iv) Accuracy of the information reflected in the suggestion.

(v) Feasibility of implementation.

(vi) Nature and complexity of the suggestion.

(vii) Any other factors that appear to be relevant.

(2) *Evaluation time limit.* CMS concludes the evaluation process in a reasonable amount of time, not to exceed 2 years from the receipt date, taking into consideration the complexity of the suggestion, the number of possible implementation strategies, and CMS's current workload.

(g) *Basis for reward payment*—(1) *General rule.* If CMS determines that it is appropriate to make a reward payment for a suggestion adopted in whole or in part, that results in improved efficiency and monetary savings to the Medicare program, the payment is based on—

(i) The actual first-year net savings to the Medicare program, or

(ii) The average annual net savings to the Medicare program expected to be realized over a period of not more than 3 years if—

(A) An improvement is expected to yield monetary savings for more than 1 year and implementation involves substantial costs; or

(B) Monetary savings are negligible in the first year but are expected to substantially increase in subsequent years.

(2) *Reward payment amount.* CMS determines the amount of a reward payment using the following formula:

(i) Net savings from $1,000 to $10,000—10 percent of the savings, with a minimum award amount of $100;

(ii) Net savings of $10,001 to $100,000—$1,000 for the first $10,000 of savings, plus 3 percent of the net savings over $10,000;

(iii) Net savings of more than $100,000—$3,700 for the first $100,000 of savings, plus 0.5 percent of savings over $100,000, with a maximum award amount of $25,000.

(h) *Adoption of suggestion and issuance of reward payment*—(1) *Adoption.* Upon completing its evaluation, CMS decides whether to adopt a suggestion. If CMS receives the same or an overlapping suggestion from two or more unrelated parties, CMS will consider a reward only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment.* After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions.* When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(l) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

PART 421—MEDICARE CONTRACTING

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

Subpart A—Scope, Definitions, and General Provisions

§ 421.1 Basis, applicability, and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act:

Section 1124—Requirements for disclosure of certain information.

Sections 1816 and 1842—Provisions relating to the administration of Parts A and B.

Section 1893—Requirements for protecting the integrity of the Medicare program.

(b) *Applicability.* The provisions of this part apply to agreements with Part A (Hospital Insurance) fiscal intermediaries that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, contracts with Part B (Supplementary Medical Insurance) carriers that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, and contracts with Medicare integrity program contractors that perform program integrity functions.

(c) *Scope.* The scope of this part—

(1) Specifies that CMS may perform certain functions directly or by contract.

(2) Specifies criteria and standards CMS uses in evaluating the performance of fiscal intermediaries' successor entities and in assigning or reassigning a provider or providers to particular fiscal intermediaries.

(3) Provides the opportunity for a hearing for fiscal intermediaries and carriers affected by certain adverse actions.

(4) Provides adversely affected fiscal intermediaries an opportunity for judicial review of certain hearing decisions.

(5) Sets forth requirements related to contracts with Medicare integrity program contractors.

[72 FR 48886, Aug. 24, 2007]

§ 421.3 Definitions.

As used in this part—

Intermediary means an entity that has a contract with CMS (under statutory provisions in effect prior to October 1, 2005) to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the prospective payment system for hospitals) and to perform other related functions. For purposes of applying the performance criteria in § 421.120 and the performance standards in § 421.122 and any adverse action resulting from that application, the term ''intermediary'' also means a Blue Cross plan that has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[71 FR 68228, Nov. 24, 2006]

§ 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

Subpart B—Intermediaries

§ 421.100 Intermediary functions.

An agreement between CMS and an intermediary specifies the functions to be performed by the intermediary.

(a) *Mandatory functions.* The contract must include the following functions:

(1) Determining the amount of payments to be made to providers for covered services furnished to Medicare beneficiaries.

(2) Making the payments.

(b) *Additional functions.* The contract may include any or all of the following functions:

(1) Any or all of the program integrity functions described in § 421.304, provided the intermediary is continuing those functions under an agreement entered into under section 1816 of the Act that was in effect on August 21, 1996, and they do not duplicate work

being performed under a Medicare integrity program contract.

(2) Undertaking to adjust incorrect payments and recover overpayments when it is determined that an overpayment was made.

(3) Furnishing to CMS timely information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(4) Establishing and maintaining procedures as approved by CMS for the redetermination of payment determinations.

(5) Maintaining records and making available to CMS the records necessary for verification of payments and for other related purposes.

(6) Upon inquiry, assisting individuals for matters pertaining to an intermediary agreement.

(7) Serving as a channel of communication to and from CMS of information, instructions, and other material as necessary for the effective and efficient performance of an intermediary agreement.

(8) Undertaking other functions as mutually agreed to by CMS and the intermediary.

(c) *Dual intermediary responsibilities.* Regarding the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or the hospice and its parent provider will be served by different intermediaries, the designated regional intermediary will process bills, make coverage determinations, and make payments to the HHAs and the hospices. The intermediary or Medicare integrity program contractor serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

[72 FR 48886, Aug. 24, 2007]

§ 421.103 Payment to providers.

Providers are assigned to intermediaries in accordance with § 421.104. As the Medicare Administrative Contractors (MACs) are implemented, providers are reassigned from intermediaries to MACs in accordance with § 412.404 of this chapter.

[71 FR 68228, Nov. 24, 2006]

§ 421.104 Assignment of providers of services to intermediaries during transition to Medicare Administrative Contractors (MACs).

(a) Beginning October 1, 2005, CMS assigns providers of services and other entities that may bill Part A benefits to intermediaries in a manner that will best support the transition to Medicare Administrative Contractors (MACs) under section 1874A of the Act in accordance with subpart E of this part.

(b) These providers of services and other entities must continue to bill the intermediary that they were billing prior to October 1, 2005, until one of the following events occurs:

(1) The intermediary's agreement with CMS ends, and the provider or entity is directed by CMS to bill another CMS contractor.

(2) The provider or entity is assigned to a MAC that has begun to administer claims within the geographic locale of the provider or entity.

(3) CMS directs the provider or entity to begin billing another CMS contractor in order to support the implementation of MACs under section 1874A of the Act and subpart E of this part.

(c) New providers of services and new entities will be assigned to the intermediary serving their geographic locale if no MAC has begun to administer Medicare claims in the locale. These providers or entities must continue to bill the intermediary until one of the events in paragraph (b) of this section occurs.

(d) Providers or entities will only be granted exceptions to the provisions of paragraphs (b) or (c) of this section if CMS deems the exception to be in the compelling interest of the Medicare program.

(e) CMS will notify the provider or entity, the outgoing intermediary, and the newly assigned intermediary of assignment or reassignment decisions.

[71 FR 68228, Nov. 24, 2006]

§ 421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§ 421.120) and standards (§ 421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, the Secretary may make determinations with respect to the termination of an intermediary agreement, and CMS may make determinations with respect to renewal of an intermediary agreement under § 421.110.

(b) When taking the actions specified in paragraph (a) of this section, the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria specified in § 421.120 and the performance standards specified in § 421.122.

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994; 71 FR 68229, Nov. 24, 2006]

§ 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will be in the best interests of the Medicare program.

[71 FR 68229, Nov. 24, 2006]

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of

the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost incurred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) CMS has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between CMS and a carrier specifies the functions to be performed by the carrier. The contract may include any or all of the following functions:

(a) Any or all of the program integrity functions described in § 421.304 provided the following conditions are met:

(1) The carrier is continuing those functions under a contract entered into under section 1842 of the Act that was in effect on August 21, 1996.

(2) The functions do not duplicate work being performed under a Medicare integrity program contract, except that the function related to developing and maintaining a list of DME may be performed under both a carrier contract and a Medicare integrity program contract.

(b) Receiving, disbursing, and accounting for funds in making payments for services furnished to eligible individuals within the jurisdiction of the carrier.

(c) Determining the amount of payment for services furnished to an eligible individual.

(d) Undertaking to adjust incorrect payments and recover overpayments when it is determined that an overpayment was made.

(e) Furnishing to CMS timely information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(f) Maintaining records and making available to CMS the records necessary for verification of payments and for other related purposes.

(g) Establishing and maintaining procedures under which an individual enrolled under Part B is granted an opportunity for a redetermination.

(h) Upon inquiry, assisting individuals with matters pertaining to a carrier contract.

(i) Serving as a channel of communication to and from CMS of information, instructions, and other material as necessary for the effective and efficient performance of a carrier contract.

(j) Undertaking other functions as mutually agreed to by CMS and the carrier.

[72 FR 48886, Aug. 24, 2007]

§ 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

§ 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost

which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a)(12) and 1834(h) of the Act, which authorize the Secretary to designate one carrier for one or more entire regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics, and other supplies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation.* (1) The boundaries of the initial four regions for processing claims described in paragraph (b) of this section contain the following States and territories:

(i) Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware.

(ii) Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota.

(iii) Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico, and the Virgin Islands.

(iv) Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa, and Missouri.

(2) CMS has the option to modify the number and boundaries of the regions established in paragraph (c)(1) of this section based on appropriate criteria and considerations, including the effect of the change on beneficiaries and DMEPOS suppliers. To announce changes, CMS publishes a notice in the FEDERAL REGISTER that delineates the regional boundary or boundaries changed, the States and territories affected, and supporting criteria or considerations.

(d) *Criteria for designating regional carriers.* CMS designates regional carriers

to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program. In making this designation, CMS will award regional carrier contracts in accordance with applicable law and will consider some or all of the following criteria—

(1) Timeliness of claim processing;

(2) Cost per claim;

(3) Claim processing quality;

(4) Experience in claim processing, and in establishing local medical review policy; and

(5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier must process claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within that carrier's region as designated under paragraph (c) of this section. When processing the claims, the carrier must use the payment rates applicable for the State of residence of the beneficiary, including a qualified Railroad Retirement beneficiary. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) CMS notifies affected Medicare beneficiaries and suppliers when it designates a regional carrier (in accordance with paragraph (d) of this section) to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated under paragraph (c) of this section).

(3) CMS may contract for the performance of National Supplier Clearinghouse functions through a contract amendment to one of the DME regional carrier contracts or through a contract amendment to any Medicare carrier contract under § 421.200.

(4) CMS periodically recompetes the contracts for the DME regional carriers. CMS also periodically recompetes the National Supplier Clearinghouse function.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993; 70 FR 9239, Feb. 25, 2005]

§ 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in § 421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

§ 421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the carrier in response to a claim that it is unable to process within established time limits.

(c) *When advance payments may be made.* An advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in

section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) A carrier must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid the supplier.

(ii) ''Historical data'' are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a ''payment'' under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed

to CMS's discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier's reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier's right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier's reconciliation of amounts advanced and recouped is not an initial determination as defined at § 405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

[61 FR 49275, Sept. 19, 1996]

Subpart D—Medicare Integrity Program Contractors

SOURCE: 72 FR 48886, Aug. 24, 2007, unless otherwise noted.

§ 421.300 Basis, applicability, and scope.

(a) *Basis.* This subpart implements section 1893 of the Act, which requires CMS to protect the integrity of the Medicare program by entering into contracts with eligible entities to carry out Medicare integrity program functions. The provisions of this subpart are based on section 1893 of the Act (and, where applicable, section 1874A of the Act) and the acquisition regulations set forth at 48 CFR chapters 1 and 3.

(b) *Applicability.* This subpart applies to entities that seek to compete or receive award of a contract under section 1893 of the Act, including entities that perform functions under this subpart emanating from the processing of claims for individuals entitled to benefits as qualified railroad retirement beneficiaries.

(c) *Scope.* The scope of this subpart follows:

(1) Defines the types of entities eligible to become Medicare integrity program contractors.

(2) Identifies the program integrity functions a Medicare integrity program contractor performs.

(3) Describes procedures for awarding and renewing contracts.

(4) Establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest.

(5) Prescribes responsibilities.

(6) Sets forth limitations on contractor liability.

§ 421.302 Eligibility requirements for Medicare integrity program contractors.

(a) CMS may enter into a contract with an entity to perform the functions described in § 421.304 if the entity meets the following conditions:

(1) Demonstrates the ability to perform the Medicare integrity program contractor functions described in § 421.304. For purposes of developing and periodically updating a list of DME under § 421.304(e), an entity is deemed to be eligible to enter into a contract under the Medicare integrity program to perform the function if the entity is a carrier with a contract in effect under section 1842 of the Act.

(2) Agrees to cooperate with the OIG, the DOJ, and other law enforcement agencies, as appropriate, including making referrals, in the investigation and deterrence of potential fraud and abuse of the Medicare program.

(3) Complies with conflict of interest provisions in 48 CFR chapters 1 and 3, and is not excluded under the conflict of interest provision at § 421.310.

(4) Maintains an appropriate written code of conduct and compliance policies that include, but are not limited to, an enforced policy on employee conflicts of interest.

(5) Meets other requirements that CMS establishes.

(b) A MAC as described in section 1874A of the Act may perform any or all of the functions described in § 421.304, except that the functions may not duplicate work being performed

under a Medicare integrity program contract.

(c) If a MAC performs any or all functions described in § 421.304, CMS may require the MAC to comply with any or all of the requirements of paragraph (a) of this section as a condition of its contract.

§ 421.304 Medicare integrity program contractor functions.

The contract between CMS and a Medicare integrity program contractor specifies the functions the contractor performs. The contract may include any or all of the following functions:

(a) Conducting medical reviews, utilization reviews, and reviews of potential fraud related to the activities of providers of services and other individuals and entities (including entities contracting with CMS under parts 417 and 422 of this chapter) furnishing services for which Medicare payment may be made either directly or indirectly.

(b) Auditing, settling and determining cost report payments for providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 of this chapter), as necessary to help ensure proper Medicare payment.

(c) Determining whether a payment is authorized under title XVIII, as specified in section 1862(b) of the Act, and recovering mistaken and conditional payments under section 1862(b) of the Act.

(d) Educating providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues.

(e) Developing, and periodically updating, a list of items of DME that are frequently subject to unnecessary utilization throughout the contractor's entire service area or a portion of the area, in accordance with section 1834(a)(15)(A) of the Act.

§ 421.306 Awarding of a contract.

(a) CMS awards and administers Medicare integrity program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, all other applicable laws, and all applicable regulations. These requirements for awarding Medicare integrity program contracts are used as follows:

(1) When entering into new contracts.

(2) When entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 1816(l) or section 1842(c) of the Act, respectively.

(3) At any other time CMS considers appropriate.

(b) CMS may award an entity a Medicare integrity program contract by transfer if all of the following conditions apply:

(1) Through approval of a novation agreement in accordance with the requirements of the Federal Acquisition Regulation (FAR), CMS recognizes the entity as the successor in interest to a fiscal intermediary agreement or carrier contract under which the fiscal intermediary or carrier was performing activities described in section 1893(b) of the Act on August 21, 1996.

(2) The fiscal intermediary or carrier continued to perform Medicare integrity program activities until transferring the resources to the entity.

(c) An entity is eligible to be awarded a Medicare integrity program contract only if it meets the eligibility requirements specified in § 421.302; 48 CFR chapters 1 and 3; and other applicable laws and regulations.

§ 421.308 Renewal of a contract.

(a) *General.* (1) CMS specifies an initial contract term in the Medicare integrity program contract.

(2) Contracts under this subpart may contain renewal clauses.

(3) CMS may, but is not required to, renew the Medicare integrity program contract, without regard to any provision of law requiring competition, as it determines to be appropriate, by giving the contractor notice, within timeframes specified in the contract, of its intent to do so.

(b) *Conditions for renewal of contract.* CMS may renew a Medicare integrity program contract if all of the following conditions are met:

(1) The Medicare integrity program contractor continues to meet the requirements established in this subpart.

(2) The Medicare integrity program contractor meets or exceeds the performance requirements established in its current contract.

(3) It is in the best interest of the government.

(c) *Nonrenewal of a contract.* If CMS does not renew a contract, the contract ends in accordance with its terms.

§ 421.310 Conflict of interest requirements.

Offerors for MIP contracts and MIP contractors are subject to the following:

(a) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance specified under 48 CFR subpart 9.5.

(b) The standards and requirements as are contained in each individual contract awarded to perform section 1893 of the Act functions.

§ 421.312 Conflict of interest resolution.

(a) *Review Board.* CMS may establish and convene a Conflicts of Interest Review Board to assist the contracting officer in resolving organizational conflicts of interest.

(b) *Resolution*—(1) *Pre-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict precludes award of a contract to the offeror.

(iii) It is in the best interest of the government to award a contract to the offeror (in accordance with 48 CFR subpart 9.503) even though a conflict of interest exists.

(2) *Post-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

(ii) The conflict requires that CMS modify an existing contract.

(iii) The conflict requires that CMS terminate or not renew an existing contract.

(iv) It is in the best interest of the government to continue the contract even though a conflict of interest exists.

§ 421.316 Limitation on Medicare integrity program contractor liability.

(a) A MIP contractor, a person or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a MIP contractor is not in violation of any criminal law or civilly liable under any law of the United States or of any State (or political subdivision thereof) by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart, provided due care was exercised in that performance and the contractor has a contract with CMS under this subpart.

(b) CMS pays a contractor, a person or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if the following conditions are met:

(1) The suit, action, or proceeding was brought against the contractor, such person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS under this subpart.

(2) The funds are available.

(3) The expenses are otherwise allowable under the terms of the contract.

Subpart E—Medicare Administrative Contractors (MACs)

SOURCE: 71 FR 68229, Nov. 24, 2006, unless otherwise noted.

§ 421.400 Statutory basis and scope.

(a) *Statutory basis.* This subpart implements section 1874A of the Act, which provides for the transition of the claims processing functions and operations for both Medicare Part A and Part B intermediaries and carriers to Medicare Administrative Contractors (MACs). The transition will occur between October 1, 2005, and October 1,

2011. MACs will be fully operational in distinct, nonoverlapping geographic jurisdictions by October 1, 2011.

(b) *Scope.* This subpart specifies the requirements under which providers and suppliers will be assigned to MACs.

§ 421.401 Definitions.

For purposes of this subpart—

Appropriate MAC means a MAC that has a contract under section 1874A of the Act to perform a particular Medicare administrative function in relation to:

(1) A particular individual entitled to benefits under Part A or enrolled under Part B, or both;

(2) A specific provider of services or supplier; or

(3) A class of providers of services or suppliers.

Medicare Administrative Contractor (MAC) means an agency, organization, or other person with a contract under section 1874A of the Act.

§ 421.404 Assignment of providers and suppliers to MACs.

(a) *Definitions.* As used in this section—

Chain provider means a group of two or more providers under common ownership or control.

Common control exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.

Common ownership exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.

Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) means the types of services specified in § 421.210(b).

Eligible provider means a hospital, skilled nursing facility, or critical access hospital that meets the definition of a provider under § 400.202 of this chapter.

Home office means the entity that provides centralized management and administrative services to the individual providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services.

Ineligible provider means a provider under § 400.202 of this chapter that is not an eligible provider.

Medicare benefit category means a category of covered benefits under Part A or Part B of the Medicare program (for example, inpatient hospital services, post-hospital extended care services, and physicians'services).

Provider has the same meaning as specified under § 400.202 of this chapter.

Qualified chain provider means a chain provider comprised of—

(1) 10 or more eligible providers collectively totaling 500 or more certified beds; or

(2) 5 or more eligible providers collectively totaling 300 or more certified beds, with eligible providers in 3 or more contiguous States.

Supplier has the same meaning as specified in § 400.202 of this chapter.

(b) *Assignment of providers to MACs.* (1) Providers enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the provider's covered services for the geographic locale in which the provider is physically located.

(2) Qualified chain providers may request and receive an exception from the requirement of paragraph (b)(1) of this section from CMS. Upon CMS'approval, a qualified chain provider may enroll with and bill on behalf of the eligible providers under its common ownership or common control to the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the eligible providers'covered services for the geographic locale in which the qualified chain provider's home office is physically located.

(3) As MAC contractors become available, qualified chain providers, granted approval by CMS to enroll with and bill a single intermediary on behalf of their eligible member providers prior to October 1, 2005, will be assigned at an appropriate time to the MAC contracted by CMS to administer claims for the applicable Medicare benefit category for the geographic locale in which the

chain provider's home office is physically located. The qualified chain provider will not need to request an exception to the requirement of paragraph (b)(1) of this section in order for this assignment to take effect.

(4) CMS may grant an exception to the requirement of paragraph (b)(1) of this section to eligible providers that are not under the common ownership or common control of a qualified chain provider, as well as ineligible providers, only if CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

(c) *Assignment of suppliers to MACs.* (1) Suppliers, including physicians and other practitioners, but excluding suppliers of DMEPOS, enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the supplier's covered services for the geographic locale in which the supplier furnished such services.

(2) Suppliers of DMEPOS receive Medicare payment and other Medicare services from the MAC assigned to administer claims for DMEPOS for the regional area in which the beneficiary receiving the DMEPOS resides. The terms of §§ 421.210 and 421.212 continue to apply to suppliers of DMEPOS.

(3) CMS may allow a group of ESRD suppliers under common ownership and common control to enroll with the MAC contracted by CMS to administer ESRD claims for the geographic locale in which the group's home office is located only if—

(i) The group of ESRD suppliers requests such privileges; and

(ii) CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

Subpart F—Medical Review

SOURCE: 73 FR 55761, Sept. 26, 2008 unless otherwise noted.

§ 421.500 Medicare review function.

CMS enters into contractual agreements with intermediaries, carriers, Medicare Administrative Contractors (MACs), and program safeguard contractors (PSCs) to perform medical review functions not for benefit integrity purposes to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions.

§ 421.501 Definitions.

As used in this subpart—

Allowable charge means the dollar amount (including co-payment and deductibles) that the Medicare program will pay for a particular item or service.

Benefit integrity review means medical review of claim information and medical documentation focusing on addressing situations of potential fraud, waste and abuse.

Complex medical review means all medical review of claim information and medical documentation by a licensed medical professional, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of sustained or high level of payment error.

Contractor, as used in this subpart, means intermediaries, carriers, Medicare Administrative Contractors (MACs), and program safeguard contractors (PSCs).

Error rate means the dollar amount of allowable charges for a particular item or service billed in error as determined by complex medical review, divided by the dollar amount of allowable charges for that medically reviewed item or service.

Initial error rate means the calculation of an error rate based on the results of a probe review prior to the initiation of complex medical review.

Medical review means the process performed by a contractor to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act.

Nonclinician medical review staff means specially trained medical review staff not possessing the knowledge, skills, training, or medical expertise of a licensed health care professional.

Non-random prepayment complex medical review means the prepayment medical review of claim information and medical documentation, by a licensed

medical professional, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of sustained or high level of payment error.

Non-random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of a sustained or high level of payment error.

Postpayment medical review means medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service after a claim has been paid.

Provider-specific probe review means the complex medical review of a small sample of claims, generally 20 to 40 claims, from a specific provider or supplier for a specific billing code to confirm that or determine whether the provider or supplier is billing the program in error.

Random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service that has not been identified by data analysis techniques or probe review to have a likelihood of a sustained or high level of payment error.

Quarterly error rate means the calculation of an error rate based on the results of non-random prepayment complex medical review for a specific billing code for a specific quarter.

Service-specific probe review means the complex medical review of a sample of claims, generally 100 claims, across the providers or suppliers that bill a particular item or service to confirm that or determine whether the item or service is billed in error.

Termination of non-random prepayment complex medical review means the cessation of non-random prepayment complex medical review.

§ 421.505 Termination and extension of non-random prepayment complex medical review.

(a) *Timeframe that a provider or supplier must be on non-random prepayment complex medical review.* There is no minimum timeframe that a provider or supplier must be on review. Except for cases described in paragraph (b) of this section, a contractor must terminate a provider or supplier from non-random prepayment complex medical review—

(1) No later than 1 year following the initiation of non-random prepayment complex medical review; or

(2) When calculation of the error rate indicates that the provider or supplier has reduced its initial error rate by 70 percent or more. A contractor must review claims for a specific billing code aberrancy for the quarter and calculate the quarterly error rate for those claims medically reviewed in that quarter. In order for this determination to be made, the provider or supplier must submit a copy of the medical records that indicate that the items or services billed are covered, correctly coded, and are reasonable and necessary for the condition of the patient.

(3) When a provider or supplier is terminated from non-random prepayment complex medical review after 1 year of review and the contractor determines that the provider or supplier continues to have a high error rate despite educational interventions, the contractor must consider referring the provider or supplier to the contractor responsible for benefit integrity review. Contractors must also consider continuing educational interventions without performing further medical review or consider the need for post-payment medical review.

(b) *Extension of non-random prepayment complex medical review.* (1) A contractor has the discretion to extend non-random prepayment complex medical review if a provider or supplier stops billing the code under review, shifts billing to another inappropriate code to avoid proper calculation of the error rate, fails to respond to requests for medical records, or engages in any other improper claims or billing-related activity to avoid non-random prepayment complex medical review. If the reduction in the error rate is attributed to a 25 percent or greater reduction in the number of claims submitted for the specific billing code under review, non-random prepayment complex medical review for that provider or supplier may be extended.

However, if the number of claims submitted for a specific code was reduced because the provider or supplier began billing claims using a new appropriate code, or there is another legitimate explanation for the reduced number of claims billed, the contractor retains discretion to terminate from or extend a provider or supplier on non-random prepayment complex medical review.

(2) If extended medical review is necessary, contractors must notify providers and suppliers in writing the reasons for the need to perform additional prepayment complex review.

(c) *Quarterly termination evaluation.* (1) Contractors, at a minimum, must evaluate the length of time a provider or supplier has been on non-random prepayment complex medical review on a quarterly basis.

(2) A determination as to whether the provider's or supplier's initial probe review error rate for a specific billing code has been reduced by 70 percent must also be evaluated quarterly. There is no minimum timeframe that a provider or supplier must be on review.

(3) The contractor's quarterly error rate evaluations must be for the discrete quarter; a rolling error rate average over more than 1 quarter is not permitted.

(4) After the contractor determines that the provider or supplier must be terminated from non-random prepayment complex medical review, the claims processing system must be updated within 5 business days to ensure that a provider's or supplier's claims for a specific billing error are no longer suspended for non-random prepayment complex medical review.

(d) *Periodic re-evaluation.* (1) Once a provider or supplier is terminated from non-random prepayment complex medical review, contractors may periodically re-evaluate the provider or supplier's data and may place a provider or supplier that appears to have resumed a high level of payment error on non-random prepayment complex medical review.

(2) This review would only be initiated if a probe review confirms that there continues to be a high level of payment error.

(3) If there is a high level of payment error, a provider or supplier may be placed on non-random prepayment complex medical review no earlier than 6 months after termination of a previous non-random prepayment complex medical review. As set forth in §421.505(a)(3) contractors may also refer the provider or supplier to the contractor responsible for benefit integrity review or place the provider or supplier on postpayment medical review.

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Subpart A—General Provisions

SOURCE: 63 FR 35068, June 26, 1998, unless otherwise noted.

§ 422.1 Basis and scope.

(a) *Basis.* This part is based on the indicated provisions of the following sections of the Act:

1851—Eligibility, election, and enrollment.
1852—Benefits and beneficiary protections.
1853—Payments to Medicare Advantage (MA) organizations.
1854—Premiums.

1855—Organization, licensure, and solvency of MA organizations.
1856—Standards.
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1858—Special rules for MA Regional Plans.
1859—Definitions; enrollment restriction for certain MA plans.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage organizations through Medicare Advantage plans.

[63 FR 35068, June 26, 1998, as amended at 70 FR 4714, Jan. 28, 2005]

§ 422.2 Definitions.

As used in this part—

Arrangement means a written agreement between an MA organization and a provider or provider network, under which—

(1) The provider or provider network agrees to furnish for a specific MA plan(s) specified services to the organization's MA enrollees;

(2) The organization retains responsibilities for the services; and

(3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Attestation process means a CMS-developed RADV audit-related dispute process that enables MA organizations undergoing RADV audit to submit CMS-generated and physician practitioner signed attestations for medical records with missing or illegible signatures or credentials. Physicians/practitioners who documented health care services in the specific medical record under RADV review will be allowed to attest that they provided and documented the health care services evidenced in the specific medical record.

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an MA enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an MA plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Fully integrated dual eligible special needs plan means a CMS approved MA–PD dual eligible special needs plan that—

(1) Enrolls special needs individuals entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2;

(2) Provides dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization;

(3) Has a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, consistent with State policy;

(4) Coordinates the delivery of covered Medicare and Medicaid health and long-term care services using aligned care management and specialty care

network methods for high-risk beneficiaries; and

(5) Employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement.

Hierarchical condition categories (HCC) means disease groupings consisting of disease codes (currently ICD–9–CM codes) that predict average healthcare spending. HCCs represent the disease component of the enrollee risk score that are applied to MA payments.

Initial Validation Contractor (IVC) means the first level of medical record review under the RADV audit process.

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for individuals with intellectual disabilities (ICF/IID); or an inpatient psychiatric facility.

Institutionalized-equivalent means for the purpose of defining a special needs individual, an MA eligible individual who is living in the community but requires an institutional level of care. The determination that the individual requires an institutional level of care (LOC) must be made by—

(1) The use of a State assessment tool from the State in which the individual resides; and

(2) An assessment conducted by an impartial entity and having the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. In States and territories that do not have an existing institutional level of care assessment tool, the individual must be assessed using the same methodology that State uses to determine institutional level of care for Medicaid nursing home eligibility.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an MA contract.

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

MA eligible individual means an individual who meets the requirements of § 422.50.

MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

MA plan means health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan (or in individual segments of a service area, under § 422.304(b)(2)).

MA plan enrollee is an MA eligible individual who has elected an MA plan offered by an MA organization.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes

an MA MSA. A trustee may be a bank, an insurance company, or any other entity that—

(1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and

(2) Meets the requirements of § 422.262(b).

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that CMS makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS ruling. (The term does not include coverage changes mandated by statute.)

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for service payment system.

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as a mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Prescription drug plan (PDP). PDP has the definition set forth in § 423.4 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in § 423.4 of this chapter.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an MA organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an MA coordinated care plan or network PFFS plan.

RADV payment error calculation appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.

Related entity means any entity that is related to the MA organization by common ownership or control and

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

Religious Fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an MA plan that is offered by an RFB society.

Risk adjustment data validation (RADV) audit means a CMS-administered payment audit of a Medicare Advantage (MA) organization that ensures the integrity and accuracy of risk adjustment payment data.

Senior housing facility plan means an MA coordinated care plan that—

(1) Restricts enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2);

(2) Provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that CMS determines is adequate consistent with prevailing patterns of community health care referenced at § 422.112(a)(10);

(3) Provides transportation services for beneficiaries to specialty providers outside of the facility; and

(4) Was participating as of December 31, 2009 in a demonstration established by CMS for not less than 1 year.

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Severe or disabling chronic condition means for the purpose of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means an MA coordinated care plan that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV) means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 74 FR 1540, Jan. 12, 2009; 75 FR 19803, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011]

§ 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution

into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by any of the following:

(A) Health maintenance organizations (HMOs);

(B) Provider-sponsored organizations (PSOs), subject to paragraph (a)(1)(vi) of this section.

(C) Regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section.

(D) Other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS's SNP requirements and exclusively enrolls special needs individuals as defined by § 422.2 of this subpart. All MA plans wishing to offer a SNP will be required to be approved by the National Commission on Quality Assurance (NCQA) effective January 1, 2012. This approval process applies to existing SNPs as well as new SNPs joining the program. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance.

(v) A PPO plan is a plan that—

(A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;

(C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and

(D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan's standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.

(vi) In accordance with § 422.370, CMS does not waive the State licensure requirement for organizations seeking to offer a PSO.

(2) *A combination of an MA MSA plan and a contribution into the MA MSA established in accordance with § 422.262.* (i) *MA MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);

(B) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and

(C) Meets all other applicable requirements of this part.

(ii) *MA MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the MA program, or a trustee-to-trustee transfer or rollover from another MA MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *MA private fee-for-service plan.* An MA private fee-for-service plan is an MA plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Subject to paragraphs (a)(3)(ii)(A) and (B) of this section, does not vary the rates for a provider based on the utilization of that provider's services; and

(A) May vary the rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization and do not violate § 422.205 of this part.

(B) May increase the rates for a provider based on increased utilization of specified preventive or screening services.

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(iv) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

(b) *Multiple plans.* Under its contract, an MA organization may offer multiple plans, regardless of type, provided that the MA organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a waiver of the State licensing requirement). If an MA organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of MA plan.

(c) *Rule for MA Plans' Part D coverage.* (1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011]

§ 422.6 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees*—(1) *Timing of collection.* CMS collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by CMS in that fiscal year to carry out

the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2006 and each succeeding year, the applicable portion (as defined in paragraph (e) of this section) of $200 million.''

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs: C divided by A times B where—A is the total estimated January payments to all PDP sponsors subject to the assessment; B is the 9-month (January through September) assessment period; and C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

(4) If assessments reach the amount authorized for the year before the end of September, CMS discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), CMS may adjust the assessment time period and the fee percentage amount.

[65 FR 40315, June 29, 2000. Redesignated and amended at 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined in § 422.2 unless specifically noted otherwise.

(a) An individual is eligible to elect an MA plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the MA organization as an MA plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that—

(i) An individual who develops end-stage renal disease while enrolled in an MA plan or in a health plan offered by the MA organization is eligible to elect an MA plan offered by that organization;

(ii) An individual with end-stage renal disease whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, because

CMS or the MA organization terminated the MA organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another MA plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another MA plan; and

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the MA plan.

(ii) Resides outside of the service area of the MA plan and is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements of § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected MA plan, even if the individual lives outside of the MA plan service area, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements at § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form or completes another CMS-approved election method offered by the MA organization and provides information required for enrollment; and

(6) Agrees to abide by the rules of the MA organization after they are disclosed to him or her in connection with the election process.

(b) An MA eligible individual may not be enrolled in more than one MA plan at any given time.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule.* In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements.* Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50.* CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility.* If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting enrollment.* An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) *Establishing eligibility for enrollment.* A SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP.

[70 FR 4716, Jan. 28, 2005, as amended at 74 FR 1541, Jan. 12, 2009]

§ 422.53 Eligibility to elect an MA plan for senior housing facility residents.

(a) *Basic eligibility requirements.* To be eligible to elect an MA senior housing facility plan, the individual must meet both of the following:

(1) Be a resident of an MA senior housing facility defined in § 422.2.

(2) Be eligible to elect an MA plan under § 422.50.

(b) *Restricting enrollment.* An MA senior housing facility plan must restrict enrollment to only those individuals who reside in a continuing care retirement community as defined at § 422.133(b)(2).

(c) *Establishing eligibility for enrollment.* An MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS approved process.

[76 FR 21561, Apr. 15, 2011]

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition. Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule.* An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) *General requirements.* (1) An MA organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain CMS's approval of the continuation area, the marketing materials that describe the option, and the MA organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) *Specific requirements*—(1) *Continuation of enrollment benefits.* The MA organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

(2) *Reasonable access.* The MA organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet the requirement in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) *Reasonable cost sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

(4) *Protection of enrollee rights.* An MA organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements remain with the organization that is receiving payment from CMS; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the marketing materials.

(e) *Capitation payments.* CMS's capitation payments to all MA organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005]

§ 422.56 Enrollment in an MA MSA plan.

(a) *General.* An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will

reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program.* Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an MA MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the MA MSA plan may not enroll in an MA MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice benefit, supplemental insurance policies not specifically permitted under § 422.104, and retirement health benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 70 FR 4716, Jan. 28, 2005]

§ 422.57 Limited enrollment under MA RFB plans.

An RFB society that offers an MA RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§ 422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraph (a)(2) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (b)(4).

(2) MA organizations must accept elections during the open enrollment periods specified in § 422.62(a)(3), (a)(4), and (a)(5) if their MA plans are open to new enrollees.

(b) *Capacity to accept new enrollees.* (1) MA organizations may submit information on enrollment capacity of plans.

(2) If CMS determines that an MA plan offered by an MA organization has a capacity limit, and the number of MA eligible individuals who elect to enroll in that plan exceeds the limit, the MA organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the CMS determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms.* (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.2262. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(2) The MA organization must file and retain election forms for the period specified in CMS instructions.

(d) *When an election is considered to have been made.* An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections.* The MA organization must have an effective system for receiving, controlling, and processing elections. The system must meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (f)(1) of this section, the beneficiary must certify that, at the time of enrollment in the MA organization, he or she received the disclosure statement specified in § 422.111.

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 422.510(a)(5) or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to the members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special election period, as described in § 422.62(b)(4).

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 63 FR 54526, Oct. 9, 1998; 64 FR 7980, Feb. 17, 1999; 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 74 FR 1541, Jan. 12, 2009; 77 FR 22166, Apr. 12, 2012]

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods—* (1) *Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) For 2002 through 2010, except for 2006, the annual coordinated election period for the following calendar year is November 15 through December 31.

(ii) For 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006.

(iii) Beginning in 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(iv) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to Original Medicare or to a different MA plan, or from Original Medicare to an MA plan. If an individual changes his or her election to Original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005.* Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment from 2007 through 2010.* (i) Open enrollment period. For 2007 through 2010, except as provided in paragraphs (a)(5)(ii), (iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible in 2007 through 2010 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except

as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(7) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* For 2011 and subsequent years, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d).

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

(1) CMS or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior.

(3) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(4) The individual meets such other exceptional conditions as CMS may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an MA eligible individual who elects an MA plan during the initial enrollment period, as defined under section 1837(d) of the Act, that surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the MA plan.

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an MA MSA plan only during—

(A) An annual election period; or

(B) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an MA MSA plan during an annual election period and has never before elected an MA MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the MA MSA plan a signed and dated request in the form and manner prescribed by CMS or by filing the appropriate disenrollment form through

other mechanisms as determined by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4717, Jan. 28, 2005; 76 FR 21561, Apr. 15, 2011]

§ 422.64 Information about the MA program.

Each MA organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by CMS, the information necessary to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

[65 FR 40317, June 29, 2000]

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

(a) *Enrollment.* An individual who wishes to elect an MA plan offered by an MA organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an MA plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization.

(3) *Responsibilities of the MA organization.* The MA organization must—

(i) Submit a disenrollment notice to CMS within timeframes specified by CMS;

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the MA organization nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in CMS instructions.

(4) *Effect of failure to submit disenrollment notice to CMS promptly.* If the MA organization fails to submit the correct and complete notice required in paragraph (b)(3)(i) of this section, the MA organization must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(c) *Election by default: Initial coverage election period.* An individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

(2) *Reserved vacancies.* Subject to CMS's approval, an MA organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other MA eligible individuals.

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the MA organization as an MA enrollee, the individual's conversion to an MA enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

(4) *Prohibition against disenrollment.* The MA organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1) unless otherwise provided in a form and manner approved by CMS.

(6) *Submittal of information to CMS.* The MA organization must transmit the information necessary for CMS to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i) The individual changes the election under this section.

(ii) The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3) An individual enrolled in an MA plan that, as of December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) *Exception for employer group health plans.* (1) In cases when an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4718, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B.

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made

during a special election period as described in § 422.62(b), the effective date of coverage shall be determined by CMS, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Beginning in 2011, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(7), is effective the first day of the first month following the month in which the election is made.

[63 FR 35071, June 26, 1998, as amended at 65 FR 40317, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4718, Jan. 28, 2005; 76 FR 21562, Apr. 15, 2011]

§ 422.74 Disenrollment by the MA organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an MA organization may not—

(1) Disenroll an individual from any MA plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional disenrollment.* An MA organization may disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An MA organization must disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) The individual no longer resides in the MA plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(3) *Plan termination or reduction of area where plan is available*—(i) *General rule.* An MA organization that has its contract for an MA plan terminated, that terminates an MA plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an MA organization discontinues offering an MA plan in a portion of its service area, the MA organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an MA plan offered by the organization, provided that there is no other MA plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons

specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to a hearing under the MA organization's grievance procedures.

(d) *Process for disenrollment*—(1) Except as specified in paragraph (d)(1)(iv) of this section, an MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period must—

(*1*) Be at least 2 months; and

(*2*) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(iv) An MA organization may not disenroll an individual who had monthly premiums withheld per § 422.262(f)(1) and (g) of this part, or who is in premium withhold status, as defined by CMS.

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the MA plan, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vi) *No extension of grace period.* A beneficiary's enrollment in the MA plan may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(2) *Disruptive behavior*—(i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the

MA organization must inform the individual of the right to use the organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (iii), and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

(v) *CMS review of the proposed disenrollment.* CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

(3) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment.* An MA organization may disenroll the individual from an MA plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the MA plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the MA plan.

(ii) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The MA organization must report to CMS any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the MA plan's service area*—(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the MA plan's service area; or

(B) From the residence in which the individual resided at the time of enrollment in the MA plan to an area outside the MA plan's service area, for those individuals who enrolled in the MA plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule.* If the individual has not moved from the MA plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the MA organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(iii) *Exception.* If the MA plan offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after

the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (d)(4)(iii)(D) of this section consistent with Medicare access and availability requirements at § 422.112 of this part.

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, CMS notifies the MA organization that the disenrollment is effective the first day of the calendar month following the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) When an MA organization has its contract for an MA plan terminated, terminates an MA plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the MA organization must give each affected MA plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the MA program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

(e) *Consequences of disenrollment*—(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B.* An individual who is disenrolled under paragraph (b)(1)(i), (b)(1)(ii), (b)(1)(iii), or paragraph (b)(2)(ii) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4718, Jan. 28, 2005; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011]

Subpart C—Benefits and Beneficiary Protections

SOURCE: 63 FR 35077, June 26, 1998, unless otherwise noted.

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of § 422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An MA organization

must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the MA organization to provide services covered by the MA plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the MA organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the MA organization.

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An MA plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An MA organization offering an MA plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the MA plan;

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).

(e) *Multiple plans in one service area.* An MA organization may offer more than one MA plan in the same service area subject to the conditions and limitations set forth in this subpart for each MA plan.

(f) *CMS review and approval of MA benefits and associated cost sharing.* CMS reviews and approves MA benefits and associated cost sharing using written policy guidelines and requirements in this part and other CMS instructions to ensure all of the following:

(1) Medicare-covered services meet CMS fee-for-service guidelines.

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. and

(3) Benefit design meets other MA program requirements.

(4) Except as provided in paragraph (f)(5), MA local plans (as defined in § 422.2) must have an out-of pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS.

(5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) applies only to use of network providers. Such local PPO plans must include a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is—

(i) Consistent with the requirements applicable to MA regional plans at § 422.101(d)(3) of this part; and

(ii) Not greater than the annual limit set by CMS.

(6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined

by CMS to be discriminatory for such services.

(g) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of MA organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) MA organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their MA plan enrollees.

(h) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in § 422.204(b)(3).

(i) *Provider networks.* The MA plans offered by an MA organization may share a provider network as long as each MA plan independently meets the access and availability standards described at § 422.112, as determined by CMS.

(j) *Services for which cost sharing may not exceed cost sharing under Original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which MA plans' in-network cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(k) *Cost sharing for in-network preventive services.* MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(l) Coverage of DME. MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain DME brands, items, and supplies of preferred manufacturers provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all DME brands, items, and supplies of preferred manufacturers.

(ii) Its enrollees have access to all medically-necessary DME brands, items, and supplies of non-preferred manufacturers.

(iii) At the enrollees' request, it provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of DME brands, items, and supplies of non-preferred manufacturers.

(B) Provide for the repair of DME brands, items, and supplies of non-preferred manufacturers.

(iv) It makes no negative changes to its DME brands, items, and supplies of preferred manufacturers during the plan year.

(v) It treats denials of DME brands, items, and supplies of non-preferred manufacturers as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a DME brand, item, or supply of a non-preferred manufacturer as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

(vii) It provides full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage.

[65 FR 40319, June 29, 2000, as amended at 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011; 77 FR 22166, Apr. 12, 2012]

§ 422.101 Requirements relating to basic benefits.

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

(i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in §422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.

(4) Instead of applying rules in paragraph (b)(3)(ii) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

(c) MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

(d) *Special cost-sharing rules for MA regional plans.* In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible.* MA regional and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply

to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive other plan-covered items and services from the single deductible described in paragraph (d)(1)(i) of this section.

(iv) Must waive all Medicare-covered preventive services (as defined in § 410.152(l)) from the single deductible described paragraph (d)(1)(i) of this section.

(2) *Catastrophic limit.* MA regional plans are required to establish a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the Original Medicare fee-for-service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS.

(3) *Total catastrophic limit.* MA regional plans are required to establish a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section and may be no greater than the annual limit set by CMS.

(4) *Tracking of deductible and catastrophic limits and notification.* MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans.* (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

(f) *Special needs plan model of care.* (1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled—

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS will review during oversight activities.

(ii) Develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with the beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided.

(iii) Use an interdisciplinary team in the management of care.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective management structure:

(i) Target one of the three SNP populations defined in § 422.2 of this part.

(ii) Have appropriate staff (employed, contracted, or non-contracted) trained on the SNP plan model of care to coordinate and/or deliver all services and benefits.

(iii) Coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care.

(iv) Coordinate the delivery of specialized benefits and services that meet the needs of the most vulnerable beneficiaries among the three target special needs populations as defined in § 422.2 of this part, including frail/disabled beneficiaries and beneficiaries near the end of life.

(v) Coordinate communication among plan personnel, providers, and beneficiaries.

(vi) All MAOs wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

[65 FR 40319, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 76 FR 21562, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22167, Apr. 12, 2012]

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

(2) If the MA organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the MA plan.

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each MA organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the MA plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the MA plan.

(d) *Marketing of supplemental benefits.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, dual eligible special needs plans that meet a high standard of integration and minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

(1) Operated in the MA contract year prior to the MA contract year for which it is submitting its bid; and

(2) Offers its enrollees such benefits without cost-sharing or additional premium charges.

[65 FR 40320, June 29, 2000, as amended at 70 FR 4720, Jan. 28, 2005; 77 FR 22167, Apr. 12, 2012]

§ 422.103 Benefits under an MA MSA plan.

(a) *General rule.* An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

(b) *Countable expenses.* An MA organization offering an MA MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an MA organization offering an MA MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an MA MSA plan—

(1) For contract year 1999, may not exceed $6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under § 422.306(a)(2).

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part or during any other enrollments occurring after January 1.

(e) All MA organizations offering MSA plans must provide enrollees with available information on the cost and quality of services in their service area, and submit to CMS for approval a proposed approach to providing such information.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 74 FR 1541, Jan. 12, 2009; 75 FR 19805, Apr. 15, 2010]

§ 422.104 Special rules on supplemental benefits for MA MSA plans.

(a) An MA organization offering an MA MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in § 422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that CMS may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an HMO plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* MA organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The MA organization must provide to beneficiaries enrolling in a plan with a POS benefit an ''evidence of coverage'' document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not

covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS-related data.* An MA organization that offers a POS benefit through an HMO plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005; 75 FR 19805, Apr. 15, 2010]

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an MA organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an MA plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an MA plan, the enrollees must be provided the same benefits as all other enrollees in the MA plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the MA plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the MA program apply to the MA plan coverage and benefits provided to enrollees eligible for benefits under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an MA plan, which are not part of the MA plan, are not subject to review or approval by CMS.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate CMS review under the Medicaid program. MA plan benefits provided to individuals entitled to Medicaid benefits provided by the MA organization under a contract with the State Medicaid agency are subject to MA rules and requirements.

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the MA basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the MA plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

(c) *Waiver or modification of contracts with MA organizations.* (1) MA organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, MA plans under contracts between MA organizations and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an employer-sponsored group MA plan (including an MA–PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the

labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

(4) An employer-sponsored group MA plan means MA coverage offered to retirees who are Medicare eligible individuals under employment-based retiree health coverage, as defined in paragraph (d)(5) of this section, approved by CMS as an MA plan.

(5) Employment-based retiree coverage means coverage of health care costs under a group health plan, as defined in paragraph (d)(6) of this section, based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

(6) Group health plans include plans as defined in section 607(1) of ERISA, (29 U.S.C. 1167(1)). They also include the following plans:

(i) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under 5 U.S.C. 89 (the Federal Employee Health Benefit Plan (FEHBP)).

(ii) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(iii) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(iv) Any of the following plans:

(A) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93.

(B) A health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2).

(C) A health savings account (HSA) as defined in Code section 223.

(D) An Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.1003(b), for governmental plans or church plans).

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4721, Jan. 28, 2005; 76 FR 21562, Apr. 15, 2011]

§ 422.107 Special needs plans and dual-eligibles: Contract with State Medicaid Agency.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual-eligible individuals.

(b) *General rule.* MA organizations seeking to offer a special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. Such benefits may include long-term care services consistent with State policy.

(c) *Minimum contract requirements.* At a minimum, the contract must document—

(1) The MA organization's responsibility, including financial obligations,

to provide or arrange for Medicaid benefits.

(2) The category(ies) of eligibility for dual-eligible beneficiaries to be enrolled under the SNP, as described under the Statute at sections 1902(a), 1902(f), 1902(p), and 1905.

(3) The Medicaid benefits covered under the SNP.

(4) The cost-sharing protections covered under the SNP.

(5) The identification and sharing of information on Medicaid provider participation.

(6) The verification of enrollee's eligibility for both Medicare and Medicaid.

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

(d) *Date of Compliance.* (1) Effective January 1, 2010—

(i) MA organizations offering a new dual-eligible SNP must have a State Medicaid agency contract.

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

(2) [Reserved]

[73 FR 54248, Sept. 18, 2008, as amended at 76 FR 21563, Apr. 15, 2011]

§ 422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(b) *Responsibilities of the MA organization.* The MA organization must, for each MA plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Identify the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

(c) *Collecting from other entities.* The MA organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an MA organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the MA organization may bill, or authorize a provider to bill any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An MA organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005; 75 FR 19805, Apr. 15, 2010]

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) *Definitions.* The term *significant cost*, as it relates to a particular NCD or legislative change in benefits, means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is $100,000; and

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in § 422.308(a).

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

(b) *General rule.* If CMS determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost described in paragraph (a) of this section, a MA organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the ''significant cost'' threshold described in § 422.109(a), the MA organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective.* Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the MA organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the MA organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

(iii) Any service that is already a Medicare-covered service and included in the annual MA capitation rate or previously adjusted payments; and

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective.* For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the MA organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the MA organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. MA organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will

be responsible for MA plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

[68 FR 50856, Aug. 22, 2003, as amended at 70 FR 4721, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

[63 FR 35077, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee electing an MA plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

(b) *Content of plan description.* The description must include the following information:

(1) *Service area.* The MA plan's service area and any enrollment continuation area.

(2) *Benefits.* The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MA-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

(ii) For an MA MSA plan, the benefits under other types of MA plans; and

(iii) For a Special Needs Plan for dual-eligible individuals, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

(iv) The availability of the Medicare hospice option and any approved hospices in the service area, including those the MA organization owns, controls, or has a financial interest in.

(3) *Access.* (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) *Emergency coverage.* Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

(iii) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

(iv) The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the MA plan.

(6) *Supplemental benefits.* Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules.* Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The MA organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality improvement program.* A description of the quality improvement program required under § 422.152.

(10) Disenrollment rights and responsibilities.

(11) *Catastrophic caps and single deductible.* MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

(12) *Claims information.* CMS may require an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an MA plan, an MA organization must provide to the individual the following information:

(1) The information required in paragraph (f) of this section.

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as

(i) Grievances according to § 422.564; and

(ii) Appeals according to § 422.578 et. seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan.

(d) *Changes in rules.* If an MA organization intends to change its rules for an MA plan, it must:

(1) Submit the changes for CMS review under the procedures of § 422.80.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the MA program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Potential for contract termination.* The fact that an MA organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's MA plan.

(5) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

(v) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vi) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(vii) The coverage of emergency and urgently needed services.

(6) *Premiums.* (i) The MA monthly basic beneficiary premiums.

(ii) The MA monthly supplemental beneficiary premium.

(iii) The reduction in Part B premiums, if any.

(7) The plan's service area.

(8) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(9) *Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in § 422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(g) CMS may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

(h) *Provision of specific information.* Each MA organization must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include all of the following:

(1) A toll-free customer service call center that meets all of the following:

(i) Is open during usual business hours.

(ii) Provides customer telephone service in accordance with standard business practices.

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(2) An Internet Web site that includes, at a minimum the following:

(i) The information required in paragraph (b) of this section.

(ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

(3) The provision of information in writing, upon request.

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. The cards must comply with standards established by CMS.

[63 FR 35077, June 26, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40321, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4722, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 73 FR 54220, 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012]

§ 422.112 Access to services.

(a) *Rules for coordinated care plans.* An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network.* (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the MA organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in § 422.2). The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

(4) *Service area expansion.* If seeking a service area expansion for an MA plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(5) *Credentialed providers.* Demonstrate to CMS that its providers in an MA plan are credentialed through the process set forth at § 422.204(a).

(6) *Written standards.* Establish written standards for the following:

(i) Timeliness of access to care and member services that meet or exceed standards established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary.

(ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

(iii) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(7) *Hours of operation.* Ensure that—

(i) The hours of operation of its MA plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(8) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(9) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

(10) *Prevailing patterns of community health care delivery.* MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

(b) *Continuity of care.* MA organizations offering coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers that include—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services; and

(4) Procedures to ensure that the MA organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that—

(i) The MA organization makes a ''best-effort'' attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the MA organization, taking into account professional standards; and

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(6) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services.

(5) The hospital that is an essential hospital under this paragraph provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

[64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4722, Jan. 28, 2005; 70 FR 76197, Dec. 23, 2005; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011]

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The MA organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services*—(1) *Definitions.* (i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

(2) *MA organization financial responsibility*. The MA organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the MA organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other MA organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency department services that CMS will determine annually, or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

(3) *Stabilized condition*. The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as ''post-stabilization care services'').

(1) *Definition*. *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *MA organization financial responsibility*. The MA organization—

(i) Is financially responsible (consistent with §422.214) for post-stabilization care services obtained within or outside the MA organization that are pre-approved by a plan provider or other MA organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the MA organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The MA organization does not respond to a request for pre-approval within 1 hour;

(B) The MA organization cannot be contacted; or

(C) The MA organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the MA organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in §422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

(3) *End of MA organization's financial responsibility*. The MA organization's financial responsibility for post-stabilization care services it has not pre-approved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An MA organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

[65 FR 40322, June 29, 2000, as amended at 70 FR 4723, Jan. 28, 2005; 76 FR 21563, Apr. 15, 2011]

§ 422.114 Access to services under an MA private fee-for-service plan.

(a) *Sufficient access.* (1) An MA organization that offers an MA private fee-for-service plan must demonstrate to CMS that it has sufficient number and range of providers willing to furnish services under the plan.

(2) Subject to paragraphs (a)(3) and (a)(4) of this section, CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Subject to paragraph (A) of section (a)(2)(ii), contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(A) For plan year 2010 and subsequent plan years, contracts or agreements with a sufficient number and range of providers to meet the access standards described in section 1852(d)(1) of the Act.

(B) [Reserved]

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(3) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan (other than a plan described in section 1857(i)(1) or (2) of the Act) that is operating in a network area (as defined in paragraph (a)(3)(i) of this section) meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(i) Network area is defined, for a given plan year, as the area that the Secretary identifies in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year as having at least 2 network-based plans (as defined in paragraph (a)(3)(ii) of this section) with enrollment as of the first day of the year in which the announcement is made.

(ii) Network-based plan is defined as a coordinated care plan as described in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes a MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

(4) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan that is described in section 1857(i)(1) or (2) of the Act meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(b) *Freedom of choice.* MA fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

(c) *Contracted network.* Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4723, Jan. 28, 2005; 73 FR 54249, Sept. 18, 2008]

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an MA organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The MA organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

[65 FR 40323, June 29, 2000]

§ 422.128 Information on advance directives.

(a) Each MA organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An MA organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the MA organization.

(1) An MA organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The MA organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the MA organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the MA organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The MA organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not

the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the MA organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An MA organization must be able to document its community education efforts.

(2) The MA organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the MA organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The MA organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of MA organizations are entitled to the protections specified in § 422.504(g).

[63 FR 35077, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.133 Return to home skilled nursing facility.

(a) *General rule.* MA plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the MA organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the MA organization.

(b) *Definitions.* In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the MA plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

(c) *Coverage no less favorable.* The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the MA plan.

(d) *Exceptions.* The requirement to allow an MA plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the MA plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

[68 FR 50857, Aug. 22, 2003, as amended at 70 FR 4723, Jan. 28, 2005]

Subpart D—Quality Improvement

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meet the requirements of paragraph (d) of this section, and address areas identified by CMS; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

(iii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64.

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(5) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(c) *Chronic care improvement program requirements.* Develop criteria for a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects.* (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan.* For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

(iii) Evaluate the continuity and coordination of care furnished to enrollees.

(iv) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years.

SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval, in accordance with CMS guidance. A SNP must conduct a quality improvement program that—

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* (1) Subject to paragraph (h)(2) of this section, MA PFFS and MSA plans are subject to requirements that may not exceed the requirements specified in § 422.152(e).

(2) For plan year 2010, MA PFFS and MSA plans are not subject to the limitations under § 422.152(e)(1)(i) and must meet the requirements using administrative claims data only.

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005; 73 FR 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011]

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

[76 FR 26546, May 6, 2011]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An MA organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) *Quality improvement.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the quality improvement projects (QIPs) and the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) The requirements listed in § 423.165 (b)(1) through (3) of this chapter for MA organizations that offer prescription drug benefit programs.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed MA organizations.* An MA organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of an MA organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the MA organization.

(3) The MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000; 70 FR 4724, Jan. 28, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011]

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting MA organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the

FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed MA organizations.

(iv) Information about any MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS—

(i) An acknowledgment of CMS's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the time-frames specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited MA organizations.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming based on accreditation no longer guarantees that the MA organization meets the MA requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

(1) The types of MA plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received

notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until the reconsideration is administratively final.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40324, June 29, 2000]

Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An MA organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the MA organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The MA organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An MA organization that operates an MA plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An MA organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees

must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4724, Jan. 28, 2005]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An MA organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An MA organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality improvement programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005]

§ 422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available to MA plan enrollees, an MA organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an MA organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an MA organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the MA organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for MA private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An MA organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52026, Sept. 1, 2005]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability.* The requirements in this section apply to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements.* Any physician incentive plan operated by an MA organization must meet the following requirements:

(1) The MA organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at

substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section.

(3) For all physician incentive plans, the MA organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis.* Substantial financial risk occurs when risk is based on the use or costs of referral services, and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold.* The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk.* The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—Withhold % = −0.75 (Bonus %) +25%.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private MA fee-for-service plans.* An MA fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—(1) *Basic rule.* The MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1–1,000	$6,000	$10,000	$3,000
1,001–5,000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	[1]	[1]	[1]

[1] None.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or

the enrollees of several MA organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Sanctions.* An MA organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.210 Assurances to CMS.

(a) Assurances to CMS. Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

(b) Disclosure to Medicare Beneficiaries. Each MA organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the MA organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

[70 FR 52026, Sept. 1, 2005]

§ 422.212 Limitations on provider indemnification.

An MA organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an MA plan also apply to the payment described in paragraph (a)(1) of this section.

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.76 concerns calculating payment for direct medical education costs.)

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it

would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organization in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 47490, Aug. 12, 2005; 76 FR 21564, Apr. 15, 2011]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) Providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees*—(1) *Contract providers* (i) Contract providers and ''deemed'' contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The MA organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(iv) The MA organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the MA private fee-for-service plan as specified in § 422.256(b)(3), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit*—(1) *Contract providers.* An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An MA organization that offers an MA private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The

MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability*—(1) *General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of §422.111(b)(12).

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The MA organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to §489.24 of this chapter, to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an MA fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the MA organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual's enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in §422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the MA organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The MA organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The MA organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in §422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credential requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in §§ 422.204(b)(1)(i) and (b)(3).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52056, Sept. 1, 2005; 70 FR 47490, Aug. 12, 2005; 70 FR 76197, Dec. 23, 2005; 73 FR 54250, Sept. 18, 2008; 77 FR 22167, Apr. 12, 2012]

§ 422.220 Exclusion of services furnished under a private contract.

An MA organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval

SOURCE: 70 FR 4725, Jan. 28, 2005, unless otherwise noted.

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(1).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary

with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years.

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually that reflects the nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c) of this part, (that is, a standardized benchmark). For local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county. The rules for determining county capitation rates are specific to a time period, as set forth at § 422.258(a). Effective 2012, the MA area-specific non-drug monthly benchmark amount is called the blended benchmark amount, and is determined according to the rules set forth under § 422.258(d) of this part.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 76 FR 21564, Apr. 15, 2011]

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(4) *Substantial differences between bids.* An MA organization's bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions.

(5) CMS may decline to accept any or every otherwise qualified bid submitted by an MA organization or potential MA organization.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly

required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at § 422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for

the counties in a plan's service area, for the purposes of adjusting payment under § 422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option;

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011]

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits and may decline to approve a bid if the plan sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans:

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(4) *Substantial differences between bids*—(i) *General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different from the MA organization's other bid submissions. In order to be considered ''substantially different,'' as provided under § 422.254(a)(4) of this subpart, each bid must be significantly different from

other plans of its plan type with respect to premiums, benefits, or cost-sharing structure.

(ii) Transition period for MA organizations with new acquisitions. After a 2-year transition period, CMS approves a bid offered by an MA organization (or by a parent organization to that MA organization) that recently purchased (or otherwise acquired or merged with) another MA organization only if it finds that the benefit package or plan costs represented by that bid are substantially different, as provided under paragraph (b)(4)(i) of this section, from any benefit package and plan costs represented by another bid submitted by the same MA organization (or parent organization to that MA organization).

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the outcome of CMS' regional benchmark calculations required under § 422.258(c) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

[63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011]

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) For MA local plans with service areas entirely within a single MA local area:

(i) For years before 2007, one-twelfth of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(ii) For years 2007 through 2010, one-twelfth of the applicable amount determined under section 1853(k)(1) of the Act for the area for the year, adjusted as appropriate for the purpose of risk adjustment.

(iii) For 2011, one-twelfth of the applicable amount determined under 1853(k)(1) for the area for 2010.

(iv) Beginning with 2012, one-twelfth of the blended benchmark amount described in paragraph (d) of this section, subject to paragraph (d)(8) of this section and adjusted as appropriate for the purpose of risk adjustment.

(2) For MA local plans with service areas including more than one MA local area, an amount equal to the weighted average of amounts described in paragraph (a)(1) of this section for the year for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion

of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the amount determined under paragraph (a) of this section for the year by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

(d) *Determination of the blended benchmark amount*—(1) *General rules.* For the purpose of paragraphs (a) and (b) of this section, the term blended benchmark amount for an area for a year means the sum of two components: the applicable amount determined under section 1853(k)(1) of the Act and the specified amount determined under section 1853(n)(2) of Act. The weights for each component are based on the phase-in period assigned each area, as described in paragraphs (d)(8) and (d)(9) of this section. At the conclusion of an area's phase-in period, the blended benchmark for an area for a year equals the section 1853(n)(2) of the Act specified amount described in paragraph (d)(2) of this section. The blended benchmark amount for an area for a year (which takes into account paragraph (d)(8) of this section), cannot exceed the applicable amount described in paragraph (d)(2) of this section that would be in effect but for the application of this paragraph.

(2) *Applicable amount.* For the purpose of paragraphs (a) and (b) of this section, the applicable amount determined under section 1853(k)(1) of the Act for a year is—

(i) In a rebasing year (described at § 422.306(b)(2), an amount equal to the greater of the average FFS expenditure amount at § 422.306(b)(2) for an area for a year and the minimum percentage increase rate at § 422.306(a) for an area for a year.

(ii) In a year when the amounts at § 422.306(b)(2) are not rebased, the minimum percentage increase rate at § 422.306(a) for the area for the year.

(iii) In no case the blended benchmark amount for an area for a year, determined taking into account paragraph (d)(8) of this section, be greater than the applicable amount at paragraph (d)(2) of this section for an area for a year.

(iv) Paragraph (d) of this section does not apply to the PACE program under section 1894 of Act.

(3) *Specified amount.* For the purpose of paragraphs (a) and (b) of this section, the specified amount under section 1853(n)(2) of the Act is the product of the base payment amount for an area for a year (adjusted as required under § 422.306(c)) multiplied by the applicable percentage described in paragraph (d)(5) of this section for an area for a year.

(4) *Base payment amount.* The base payment amount is as follows:

(i) For 2012, the average FFS expenditure amount specified in § 422.306(b)(2), determined for 2012.

(ii) For subsequent years, the average FFS expenditure amount specified in § 422.306(b)(2).

(5) *Applicable percentage.* Subject to paragraph (d)(7) of this section, the applicable percentage is one of four values assigned to an area based on Secretary's determination of the quartile ranking of the area's average FFS expenditure amount (described at § 422.306(b)(2) and adjusted as required at § 422.306(c)), relative to this amount for all areas.

(i) For the 50 States or the District of Columbia, a county with an average FFS expenditure amount adjusted under § 422.306(c) that falls in the—

(A) Highest quartile of such rates for all areas for the previous year receives an applicable percentage of 95 percent;

(B) Second highest quartile of such rates for all areas for the previous year receives an applicable percentage of 100 percent;

(C) Third highest quartile of such rates for all areas for the previous year receives an applicable percentage of 107.5 percent; or

(D) Lowest quartile of such rates for all areas for the previous year receives an applicable percentage of 115 percent.

(ii) To determine the applicable percentages for a territory, the Secretary ranks such areas for a year based on the level of the area's § 422.306(b)(2) amount adjusted under § 422.306(c), relative to the quartile rankings computed under paragraph (d)(5)(i) of this section.

(6) *Additional rules for determining the applicable percentage.* (i) In a contract year when the average FFS expenditure amounts from the previous year were rebased (according to the periodic rebasing requirement at § 422.306(b)(2)), the Secretary must determine an area's applicable percentage based on a quartile ranking of the previous year's rebased FFS amounts adjusted under § 422.306(c).

(ii) If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year's ranking, the applicable percentage for the area in the year must be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision.

(7) *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to a 5-star rating system (based on the data collected under section 1852(e) of the Act). Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

(i) *Qualifying plan.* Beginning with 2012, a qualifying plan means a plan that had a quality rating of 4 stars or higher based on the most recent data available for such year. For a qualifying plan, the applicable percentage at paragraph (d)(5) of this section must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 3.0 percentage points.

(C) For 2014 and subsequent years, by 5.0 percentage points.

(ii) *Qualifying county*—(A) A *qualifying county* means a county that meets the following three criteria:

(*1*) Has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) of the Act for a Metropolitan Statistical Area with a population of more than 250,000.

(*2*) Of the MA-eligible individuals residing in the county, at least 25 percent of such individuals were enrolled in MA plans as of December 2009.

(*3*) Has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year.

(B) Beginning with 2012, for a qualifying plan serving a qualifying county, the increase to the applicable percentage described at paragraph (d)(7)(i) of this section must be doubled for the qualifying county.

(iii) MA organizations that fail to report data as required by the Secretary must be counted as having a rating of fewer than 3.5 stars at the plan or contract level, as determined by the Secretary.

(iv) *Application of applicable percentage increases to low enrollment contracts.* (A) For 2012, for an MA plan that the Secretary determines is unable to have a quality rating because of low enrollment, the Secretary treats this plan as a qualifying plan under paragraph (d)(7)(i) of this section.

(B) For 2013 and subsequent years, the Secretary develops a methodology to apply to MA plans with low enrollment (as defined by the Secretary) to determine whether a low enrollment contract is a qualifying plan.

(v) *Application of increases in applicable percentage to new MA plans.* A new MA plan (as defined at § 422.252) that meets criteria specified by the Secretary must be treated as a qualifying plan under paragraph (d)(7)(i) of this section, except that the applicable percentage must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 2.5 percentage points.

(C) For 2014 and subsequent years, by 3.5 percentage points.

(8) *Determination of phase-in period for the blended benchmark amount.* For 2012 through 2016, the blended benchmark amount for an area for a year depends on the phase-in period assigned to that area. The Secretary assigns one of three phase-in periods to each area: 2-year, 4 year, or 6 year. The phase-in period assigned to an area is based on the size of the difference between the 2010 applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount defined at paragraph (d)(8)(i) of this section.

(i) The projected 2010 benchmark amount is calculated once for the purpose of determining the phase-in period for an area. It is equal to one-half of the 2010 applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) modified to apply to 2010 (as described in (d)(8)(ii) of this section).

(ii) To assign a phase-in period to an area, the specified amount is modified as if it applies to 2010, and is the product of—

(A) The 2010 base payment amount adjusted as required under § 422.306(c) of this part; and

(B) The applicable percentage determined as if the reference to the ''previous year'' at paragraph (d)(5) of this section were deemed a reference to 2010 and increased as follows:

(*1*) The increase at paragraph (d)(7)(i) of this section for a qualifying plan in the area is applied as if the reference to a qualifying plan for 2012 were deemed a reference for 2010; and

(*2*) The increase at paragraph (d)(7)(ii) of this section is applied as if the determination of a qualifying county were made for 2010.

(iii) *Two-year phase-in.* An area is assigned the 2-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is less than $30.

(iv) *Four-year phase-in.* An area is assigned the 4-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $30 but less than $50.

(v) *Six-year phase-in.* An area is assigned the 6-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $50.

(9) *Impact of phase-in period on calculation of the blended benchmark amount*—(i) *Weighting for the 2-year phase-in.* (A) For 2012, the blended benchmark is the sum of one-half of the applicable amount at paragraph (d)(2) of this section and one-half of the

specified amount at paragraph (d)(3) of this section.

(B) For 2013 and subsequent years, the blended benchmark equals the specified amount.

(ii) *Weighting for the 4-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) of this section and the specified amount at paragraph (d)(2) of this section in the following proportions:

(A) For 2012, three-fourths of the applicable amount for the area for the year and one-fourth of the specified amount for the area and year.

(B) For 2013, one-half of the applicable amount for the area for the year and one-half of the specified amount for the area and year.

(C) For 2014, one-fourth of the applicable amount for the area for the year and three-fourths of the specified amount for the area and year.

(D) For 2015 and subsequent years, the blended benchmark equals the specified amount for the area and year.

(iii) *Weighting for the 6-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) and the specified amount at paragraph (d)(3) of this section in the following proportions:

(A) For 2012, five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year.

(B) For 2013, two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year.

(C) For 2014, one-half of the applicable amount for the area and year and one-half of the specified amount for the area and for year.

(D) For 2015, one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and for year.

(E) For 2016, one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and for year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.≤[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21564, Apr. 15, 2011]

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act.

(b) *Definitions.* The following definitions apply to this section:

Quality bonus payment (QBP) means—

(i) Enhanced CMS payments to MA organizations based on the organization's demonstrated quality of its Medicare contract operations; or

(ii) Increased beneficiary rebate retention allowances based on the organization's demonstrated quality of its Medicare contract operations.

Quality bonus payment (QBP) determination methodology means the formula CMS adopts for evaluating whether MA organizations qualify for a QBP.

Quality bonus payment (QBP) status means a MA organization's standing with respect to its qualification to—

(i) Receive a quality bonus payment, as determined by CMS; or

(ii) Retain a portion of its beneficiary rebates based on its quality rating, as determined by CMS.

(c) *Administrative review process for QBP status appeals.* (1) Reconsideration request. An MA organization may request reconsideration of its QBP status.

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. The error could impact an individual measure's value or the overall star rating.

(ii) The reconsideration official's decision is final and binding unless a request for an informal hearing is filed in accordance with paragraph (2) of this section.

(2) *Informal hearing request.* An MA organization may request an informal hearing on the record following the reconsideration official's decision regarding its QBP status.

(i) The MA organization seeking an appeal of the reconsideration official's decision regarding its QBP status must do so by providing written notice to CMS within 10 business days of the issuance of the reconsideration decision. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors could result in the organization's qualification for a QBP or a higher QBP.

(ii) The MA organization may not request an informal hearing of its QBP status unless it has already requested and received a reconsideration decision in accordance with paragraph (c)(1) of this section.

(iii) The informal hearing request must pertain only to the measure(s) and value(s) in question that precipitated the request for reconsideration.

(iv) The informal hearing is conducted by a CMS hearing officer on the record. The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(v) The MA organization must provide clear and convincing evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect.

(vi) The hearing officer issues the decision by electronic mail to the MA organization.

(vii) The hearing officer's decision is final and binding.

(3) *Limits to requesting an administrative review.* (i) CMS may limit the measures or bases for which a contract may request an administrative review of its QBP status.

(ii) An administrative review cannot be requested for the following: the methodology for calculating the star ratings (including the calculation of the overall star ratings); cut-off points for determining measure thresholds; the set of measures included in the star rating system; and the methodology for determining QBP determinations for low enrollment contracts and new MA plans.

(4) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the appeal of the QBP status. The officer must be an individual who did not directly participate in the initial QBP determination.

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect.

[76 FR 21566, Apr. 15, 2011]

§ 422.262 Beneficiary premiums.

(a) *Determination of MA monthly basic beneficiary premium.* (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) *Consolidated monthly premiums.* Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly

supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

(g) *Prohibition on improper billing of premiums.* MA organizations shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

(h) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment either by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

[63 FR 18134, Apr. 14, 1998, as amended at 74 FR 1541, Jan. 12, 2009]

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks.* (1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258), adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount

by a regional MA plan (defined at §422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under §422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under §422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

§422.266 Beneficiary rebates.

(a) *Calculation of rebate.* (1) For 2006 through 2011, an MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in §422.264(b) for MA local plans and §422.264(d) for MA regional plans.

(2) For 2012 and subsequent years, an MA organization must provide to the enrollee a monthly rebate equal to a specified percentage of the average per capita savings (if any) at §422.264(b) for MA local plans and §422.264(d) for MA regional plans. For 2012 and 2013, this percentage is based on a combination of the (a)(1) rule of 75 percent and the (a)(2)(ii) rules that set the percentage based on the plan's quality rating under a 5 star rating system, as determined by the Secretary under §422.258(d)(7). For 2014 and subsequent years, this percentage is determined

based only on the paragraph (a)(2)(ii) of this section.

(i) *Applicable rebate percentage for 2012 and 2013.* Subject to paragraphs (a)(2)(iii) and (iv) of this section, the transitional applicable rebate percentage is, for a year, the sum of two amounts as follows:

(A) *For 2012.* Two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan under paragraph (a)(2)(ii) of this section, based on the quality rating specified in § 422.258(d)(7).

(B) *For 2013.* One-third of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan under paragraph (d)(2)(ii) of this section, based on the quality rating at § 422.258(d)(7).

(ii) *Final applicable rebate percentage.* For 2014 and subsequent years, and subject to paragraphs (a)(2)(iii) and (iv) of this section, the final applicable rebate percentage is as follows:

(A) In the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent of the average per capita savings;

(B) In the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent of the average per capita savings.

(C) In the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent of the average per capita savings.

(iii) *Treatment of low enrollment contracts.* For 2012, in the case of a plan described at § 422.258(d)(7)(iv), the plan must be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount.

(iv) *Treatment of new MA plans.* For 2012 or a subsequent year, a new MA plan defined at § 422.252 that meets the criteria specified by the Secretary for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under § 422.258(d)(7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.≤[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21567, Apr. 15, 2011]

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

Subpart G—Payments to Medicare Advantage Organizations

SOURCE: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2))

and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees.* In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology.* ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may

request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

(f) *Separate payment for meaningful use of certified EHRs.* In the case of qualifying MA organizations, as defined in § 495.200 of this chapter, entitled to MA EHR incentive payments per § 495.220 of this chapter, such payments are made in accordance with sections 1853(l) and (m) of the Act and subpart C of part 495 of this chapter.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010]

§ 422.306 Annual MA capitation rates.

Subject to adjustments at §§ 422.308(b) and 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section, and is then adjusted to exclude the applicable phase-in percentage of the standardized costs for payments under section 1886(d)(5)(B) of the Act in the area for the year under paragraph (c) of this section.

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs.* The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education;

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs; and

(iv) Adjusted to exclude costs attributable to payments under sections 1848(o) and 1886(n) of the Act of Medicare FFS incentive payments for meaningful use of electronic health records.

(c) *Phase-out of the indirect costs of medical education from MA capitation rates.* Beginning with 2010, after the annual capitation rate for each MA local area is determined under paragraph (a)

or (b), the amount is adjusted in accordance with section 1853(k)(4) of the Act to exclude from such amount the phase-in percentage for the year of the estimated costs for payments under section 1886(d)(5)(B) of the Act in the area for the year.

[70 FR 4729, Jan. 28, 2005, as amended at 73 FR 54250, Sept. 18, 2008; 75 FR 19806, Apr. 15, 2010; 75 FR 44564, July 28, 2010]

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage.* (1) The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(2) The amount calculated in paragraph (a)(1) of this section must exclude expenditures attributable to sections 1848(a)(7) and (o) and sections 1886(b)(3)(B)(ix) and (n) of the Act.

(b) *Adjustment for over or under projection of national per capita growth percentages.* CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule.* CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation.* CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) *Application of payment rules.* For plan year 2011 and subsequent plan years, in the case of a plan described in paragraph (c)(4)(ii) of this section, the Secretary may apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of that section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(ii) *Plan described.* A plan described in this paragraph is a fully integrated dual-eligible special needs plan, as defined at § 422.2, and has a similar average level of frailty (as determined by the Secretary) as the PACE program.

(5) *Application of coding adjustment.* (i) In applying the adjustment under paragraph (c)(1) of this section for health status to payment amounts, the Secretary ensures that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between MA plans and providers under Part A and B to the extent that the Secretary has identified such differences.

(ii) In order to ensure payment accuracy, the Secretary annually conducts

an analysis of the differences described in paragraph (c)(5)(i) of this section.

(A) The Secretary completes such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years.

(B) In conducting such analysis, the Secretary uses data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(iii) In calculating each year's adjustment, the adjustment factor is as follows:

(A) For 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points.

(B) For each of the years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points.

(C) For 2019 and each subsequent year, not less than 5.7 percent.

(iv) Such adjustment is applied to risk scores until the Secretary implements risk adjustment using MA diagnostic, cost, and use data.

(6) *Improvements to risk adjustment for special needs individuals with chronic health conditions*—(i) *General rule.* For 2011 and subsequent years, for purposes of the adjustment under paragraph (c)(1) of this section with respect to individuals described in paragraph (c)(6)(ii) of the section, the Secretary uses a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score is used instead of the default risk score for new enrollees in MA plans that are not specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Act).

(ii) *Individuals described.* An individual described in this clause is a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(iii) *Evaluation.* For 2011 and periodically thereafter, the Secretary evaluates and revises the risk adjustment system under this paragraph in order to, as accurately as possible, account for—

(A) Higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness; and

(B) Costs that may be associated with higher concentrations of beneficiaries with the conditions specified in paragraph (c)(6)(iii)(A) of this section.

(iv) *Publication of evaluation and revisions.* The Secretary publishes, as part of an announcement under section 1853(b) of the Act, a description of any evaluation conducted under paragraph (c)(6)(iii) of this section during the preceding year and any revisions made under paragraph (c)(6)(iii) of this section as a result of such evaluation.

(d) *Adjustment for intra-area variations.* CMS makes the following adjustments to payments.

(1) *Intra-regional variations.* For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment.* CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments.* For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010; 76 FR 21567, Apr. 15, 2011]

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the development and application of a risk adjustment payment model.

(b) *Data collection: Basic rule.* Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data.* (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Items and services covered under the original Medicare program.

(ii) Medicare covered items and services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements.* (1) MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. CMS may specify abbreviated formats for data submission required of MA organizations.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS.

These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c). CMS also may use the data for updating risk adjustment models, calculating Medicare DSH percentages, conducting quality review and improvement activities, and for Medicare coverage purposes.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. CMS may adjust these deadlines, as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the March deadline until January 31 of the year following the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual January 31 late data submission deadline will not be accepted for the purposes of reconciliation.

[73 FR 48757, Aug. 19, 2008]

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with § 422.2 and § 422.310(e), CMS annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.

(b) *RADV audit results.* (1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors.

(3) *Medical record review appeal.* MA organizations that do not agree with the medical record review determinations for audited HCCs may appeal the medical record review determinations of the initial validation contractor to CMS in accordance with paragraph (c)(2) of this section.

(c) *RADV audit dispute and appeal processes*—(1) *Attestation process*—(i) *Submission requirements for attestations.* MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature-related or credential-related RADV errors in accordance with the attestations provisions of this section.

(B) Are not obligated to submit attestations to CMS.

(ii) *RADV audit-related errors eligible for attestation process.* CMS will only accept an attestation to support a physician or outpatient medical record with a missing signature or missing credential or both.

(iii) *RADV audit-related errors and documentation ineligible for attestation process.* (A) Attestations from providers for anything other than signature-related and credential-related errors will not be permitted.

(B) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation.* (A) CMS will provide MA organizations selected for RADV audits with attestations and accompanying instructions at the time the organization receives its audit instructions.

(B) If an organization decides to submit attestations completed by physicians or other practitioners, the MA organization must submit the attestations to CMS at the same time that the MA organization is required to submit related medical records for RADV audit.

(v) *Attestation content.* An attestation must accompany and correspond to the medical record submitted for RADV audit and must meet the following requirements:

(A) Contain only CMS-generated attestations.

(B) The CMS attestation form may not be altered unless otherwise instructed and agreed-upon in writing by CMS.

(C) Attestations must be completed and be signed and dated by the eligible risk adjustment physician/practitioner whose medical record accompanies the attestation.

(D) Attestations must be based upon medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners.

(vi) *Attestation review and determination procedures.* CMS—

(A) Reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review; and

(B) Provides written notice of its determination(s) regarding submitted attestations to the MA organization at the time CMS issues its RADV audit report.

(vii) *Effect of CMS's attestation determination.* (A) CMS' attestation determination is final.

(B) An MA organization may choose to appeal its medical record review determinations for audited HCCs following initial validation contractor review using a CMS-administered medical record review determination appeal process.

(2) *RADV-related medical record review errors and documentation eligible for medical record review determination appeal process.*—(i) *General rules.* (A) In order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow CMS rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization's request for appeal invalid.

(B) The medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV initial validation contractor (IVC).

(C) MA organizations that choose to appeal the IVC's medical record review determination(s) may only submit the IVC-audited one best medical record and IVC-reviewed attestation, previously submitted in accordance with paragraph (c)(1) of this section, to CMS for re-review.

(D) MA organizations' request for medical record review determination appeal may not include additional documentary evidence beyond the IVC-audited one best medical record and IVC-reviewed attestation.

(ii) *RADV-related audit errors and documentation ineligible for medical record review appeal process.* (A) MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS.

(B) Any other documentation submitted to CMS beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by CMS under the medical record review determination appeal process.

(C) The MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that CMS identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal.

(iii) *Manner and timing of a request for medical record review determination appeal.* (A) At the time CMS issues its IVC RADV audit report to audited MA organizations, CMS notifies these MA organizations of any RADV HCC errors that are eligible for medical record review determination appeal.

(B) MA organizations have 30 calendar days from date of issuance of the RADV audit report to file a written request with CMS for medical record review determination appeal.

(C) A request for medical record review determination appeal must specify the determinations with which the MA organization disagrees and the reasons for the request for appeal.

(iv) *Medical record review determination appeal review and notification procedures*—(A) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the medical record review determination appeal. The hearing officer need not be an ALJ.

(B) *Disqualification of hearing officer.* (*1*) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(*2*) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(*3*) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(*i*) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(*ii*) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

(v) *Hearing officer's review.* The hearing officer reviews the IVC-audited one best medical record and the IVC-reviewed attestation submitted by the MA organization to determine whether it supports overturning medical record review determination errors listed in the MA organization's IVC-level RADV audit report.

(vi) *Hearing procedures.* (A) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS hearing officer is limited to the review of the record that was before the IVC.

(vii) *Hearing officer's decision.* As soon as practical after the hearing, the hearing officer issues a decision which provides written notice of the hearing officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS.

(viii) *Computations based on hearing decision.* In accordance with the hearing officer's decision, CMS recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization.

(ix) *Effect of hearing decision.* The hearing officer's decision is final and binding, unless the MA organization requests review of the hearings officer appeal determination by the CMS Administrator.

(x) *Review by the CMS Administrator.* (A) A MA organization that has received a hearing officer decision may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's determination. A request for CMS Administrator review must be made in writing and filed with CMS.

(B) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing decision.

(C) If the CMS Administrator elects to review the hearing decision, the CMS Administrator—

(*1*) Acknowledges the decision to review the hearing decision in writing; and

(*2*) Reviews the decision and determine based upon all of the following whether the determination should be upheld, reversed, or modified:

(*i*) The hearing record.

(*ii*) Written arguments submitted by the MA organization or CMS.

(xi) *Notification of Administrator determination.* (A) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of acknowledging his or her decision to review the hearing decision.

(B) The decision of the hearing officer is final if the Administrator—

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

(3) *RADV payment error calculation appeal process.* (i) MA organizations may appeal CMS' RADV payment error calculation.

(ii) *RADV payment error-related issues ineligible for appeal.* MA organizations may not—

(A) Appeal RADV medical record review-related errors as part of the RADV payment error calculation appeal process. In accordance with paragraph (c)(2) of this section, MA organizations that wish to appeal medical record review determinations may do so following issuance of the IVC RADV audit report of findings.

(B) Introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(C) Appeal RADV errors that result from an MA organization's failure to submit a medical record.

(D) Appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.* (A) MA organizations may not appeal their RADV error calculation until any appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(B) At the time CMS issues either its IVC or post-medical record review appeal RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(C) MA organizations have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation.

(iv) *Burden of proof.* The MA organization bears the burden of proof in demonstrating that CMS failed to follow its stated RADV payment error calculation methodology.

(v) *Content of request.* The written request for reconsideration must specify the issues with which the MA organization disagrees and the reasons for the disagreements.

(A) The written request for reconsideration may include additional documentary evidence the MA organization wishes CMS to consider.

(B) CMS does not accept reconsiderations for issues with the methodology applied in any part of the RADV audit.

(vi) *Conduct of written reconsideration.* (A) In conducting the written reconsideration, CMS reviews all of the following information:

(*1*) The RADV payment error calculation.

(*2*) The evidence and findings upon which they were based.

(*3*) Any other written evidence submitted by the MA organization.

(B) CMS ensures that a third party—either within CMS or a CMS contractor—not otherwise involved in the initial RADV payment error calculation reviews the written request for reconsideration.

(C) The third party recalculates the payment error in accordance with CMS RADV payment calculation procedures described in CMS' RADV payment error calculation standard operating procedures.

(D) The third party described in paragraph (c)(3)(vi)(B) of this section provides his or her determination to a CMS reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vi) *Decision of the CMS reconsideration official.* The CMS reconsideration official informs the MA organization and CMS in writing of the decision of the CMS reconsideration official.

(vii) *Effect of the CMS reconsideration official.* The written reconsideration decision is final and binding unless a request for a hearing is filed by CMS or the appellant MA organization in accordance with paragraph (c) (4) of this section.

(4) *Right to a hearing.* CMS or a MA organization dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section.

(i) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 30 calendar days of the date CMS and the MA organization receives the CMS reconsideration officer's written reconsideration decision.

(ii) *Content of request.* The written request for hearing must include a copy of the written decision of the CMS reconsideration official and must specify the findings or issues in the reconsideration decision with which either CMS or the MA organization disagrees and the reasons for the disagreement.

(iii) *Hearing procedures.* (A) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may schedule a live or telephonic hearing on his/her own motion.

(C) The hearing is conducted by the CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made either its initial RADV payment error calculation determination or its post-medical record review appeal payment error calculation determination and when the CMS reconsideration official issued the written reconsideration decision.

(D) The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers include the authority to dismiss the appeal with prejudice or take any other action which the hearing officer considers appropriate for failure to comply with such rules and procedures.

(iv) *Decision of the CMS Hearing Officer.* The CMS hearing officer decides whether the reconsideration official's decision was correct, and sends a written decision to CMS and the MA organization, explaining the basis for the decision.

(v) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c)(5) of this section.

(vi) *Review by the CMS Administrator.* (A) CMS or a MA organization that has received a hearing officer's decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's decision.

(B) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(C) If the CMS Administrator chooses to review the case, the CMS Administrator—

(*1*) Acknowledges his or her decision to review the hearing officer's decision in writing; and

(*2*) Determines whether to uphold, reverse, or modify the Hearing Officer's decision based on his or her review of the following:

(*i*) The Hearing Officer's decision.

(*ii*) Written documents submitted by CMS or the MA organization to the Hearing Officer.

(*iii*) Any other any other information included in the record of the Hearing Officer's decision.

(D) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review.

(E) If the Administrator chooses to review, the Administrator's determination is final and binding.

(F) The decision of the hearing officer is final if the Administrator—

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

[75 FR 19806, Apr. 15, 2010; 75 FR 32859, June 10, 2010]

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 45 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the

amount the FQHC would receive for the MA enrollee from the MA organization (which includes the cost sharing amount the FQHC may charge an enrollee, as established in the contract between the FQHC and the MA organization); and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 76198, Dec. 23, 2005]

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability*. This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay*. If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay*. If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment*. (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug payment described in § 423.315 (if any). This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for

plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug payment described in § 423.315 (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments.* (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(3) Payments under subpart C of part 495 of this chapter for meaningful use of certified EHR technology are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. In applying section 1848(o) of the Act under sections 1853(l) and 1886(n)(2)of the Act under section 1853(m) of the Act, CMS determines the amount to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable for services furnished by professionals and hospitals under Parts B and A, respectively, under title XVIII of the Act.

(b) *Payments to the MA organization.* Subject to §§ 412.105(g), 413.86(d), and 495.204 of this chapter and §§ 422.109, 422.316, and 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to §§ 422.314, 422.316, 422.318, 422.320, and 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 75 FR 44654, July 28, 2010]

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H appear at 63 FR 35098, 35099, June 26, 1998.

§ 422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, (PSOs), to contract as a MA plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to the type, cost, or frequency of services furnished.

Cash equivalent means those assets excluding accounts receivable that can be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by CMS as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with CMS as an MA organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

Insolvency means a condition in which the liabilities of the debtor exceed the fair valuation of its assets.

Net worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a provider or group of affiliated providers;

(2) Provides a substantial proportion (as defined in § 422.352) of the health care services under the MA contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under § 422.356, for the provision of services that are the obligation of the PSO under the MA contract; and

(ii) Have at least a majority financial interest in the PSO.

Qualified actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made that are acceptable to CMS. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 25376, May 7, 1998; 63 FR 35098, June 26, 1998]

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a MA contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to CMS's satisfaction that it is capable of delivering to Medicare enrollees the range of services required under a contract with CMS. Each PSO must deliver a substantial proportion of those services directly through the provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare services covered under the contract.

(2) For a rural PSO, not less than 60% of Medicare services covered under the contract.

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must—

(1) Demonstrate to CMS that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more providers must demonstrate to CMS'S

satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls, is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk.* The PSO must demonstrate to CMS's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the MA contract to each affiliated provider. The PSO must demonstrate that the financial arrangements among its affiliated providers constitute ''substantial'' risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Affiliated providers agree to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest.* Majority financial interest means maintaining effective control of the PSO.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an MA plan under this subpart, CMS may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(a) The organization requests a waiver no later than November 1, 2002; and

(b) CMS determines there is a basis for a waiver under § 422.372.

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.372 Basis for waiver of State licensure.

(a) *General rule.* Subject to this section and to paragraphs (a) and (e) of § 422.374, CMS may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an MA plan.

(b) *Basis for waiver of State licensure.* Any of the following may constitute a basis for CMS's waiver of State licensure.

(1) *Failure to act timely on application.* The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an MA plan.

(3) *Denial of application based on different solvency requirements.* (i) The State has denied the application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) CMS determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by CMS to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request.* The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) CMS gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(c) *Subsequent waiver requests.* An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date.* A waiver granted under § 422.370 will be effective on the effective date of the organization's MA contract.

(e) *Consistency in application.* CMS reserves the right to revoke waiver eligibility if it subsequently determines that the organization's MA application is significantly different from the application submitted by the organization to the State licensing authority.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the MA contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

[63 FR 25377, May 7, 1998]

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other MA organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, CMS incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* CMS may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

[63 FR 25377, May 7, 1998]

§ 422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under § 422.370 must have a fiscally sound operation that meets the requirements of §§ 422.382 through 422.390.

[63 FR 25377, May 7, 1998]

§ 422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with CMS as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under § 422.384) demonstrating to CMS's satisfaction that the organization has available to it an administrative infrastructure that CMS considers appropriate to reduce, control or eliminate start-up administrative costs.

(b) After the effective date of a PSO's MA contract, a PSO must maintain a minimum net worth amount equal to the greater of—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with CMS for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with CMS; or

(4) Using the most recent financial statement filed with CMS, an amount equal to the sum of—

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application, the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's MA contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if CMS has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health care delivery assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

[63 FR 25377, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Cash-flow statements;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's MA contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in § 422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets CMS's requirements for guarantors and guarantee documents as specified in § 422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's MA contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's MA contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's MA contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter,

may notify CMS of its intent to reduce the period of advance funding of projected losses. CMS will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, CMS may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. CMS retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to CMS. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to CMS, and for periods beginning one year after the effective date of a PSO's MA contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use guarantees, letters of credit and, beginning one year after the effective date of a PSO's MA contract, other means of funding projected losses, but only in a combination or sequence that CMS considers appropriate.

[63 FR 25378, May 7, 1998, as amended at 63 FR 35098, June 26, 1998; 64 FR 71678, Dec. 22, 1999]

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, CMS will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If CMS determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, CMS will require the PSO to initiate corrective action and pay all overdue obligations.

(d) If CMS determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, CMS may require the PSO to initiate corrective action to—

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If CMS determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, CMS requires the PSO to obtain funding from alternative financial resources.

[63 FR 25378, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to CMS.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an MA contract and, thereafter, upon CMS's request, a PSO must provide CMS with proof of the insolvency deposit, such proof to be in a form that CMS considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total

health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to CMS.

(2) The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for CMS's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon CMS's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from CMS, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

[63 FR 25379, May 7, 1998]

§ 422.390 Guarantees.

(a) *General policy.* A PSO, or the legal entity of which the PSO is a component, may apply to CMS to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. CMS has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor.* To apply to use the financial resources of a guarantor, a PSO must submit to CMS—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor.* To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document.* If the guarantee request is approved, a PSO must submit to CMS a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as CMS may establish from time to time.

(e) *Reporting requirement.* A PSO must submit to CMS the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that CMS requests.

(f) *Modification, substitution, and termination of a guarantee.* A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification.* If at any time the guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each MA organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and

(c) Demonstrate to CMS that—

(1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

[70 FR 4733, Jan. 28, 2005]

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

(b) *Construction.* Nothing in this section shall be construed to exempt any MA organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization

from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

[63 FR 35099, June 26, 1998, as amended at 70 FR 4733, Jan. 28, 2005]

Subpart J—Special Rules for MA Regional Plans

SOURCE: 70 FR 4733, Jan. 28, 2005, unless otherwise noted.

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region.* The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region.* The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment.* By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas.* CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions.* CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions.* There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans.* The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis.* Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan.* An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology.* For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectible for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program

option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under §422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under §422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under §422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to §422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for

the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 76 FR 21568, Apr. 15, 2011]

Subpart K--Application Procedures and Contracts for Medicare Advantage Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions.* For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the MA organization's enrollees by hospitals and other providers, and by MA organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.310(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA organization (or contract applicant) and a first

tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an MA organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an MA organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the MA organization by common ownership or control and—

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of ''business transaction'' that, during any fiscal year of the MA organization, have a total value that exceeds $25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 77 FR 22167, Apr. 12, 2012]

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

(f) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 77 FR 22167, Apr. 12, 2012]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract or for a Specialized MA Plan for Special Needs Individuals solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A

''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an MA organization.* Any entity seeking to contract as an MA organization must:

(1) Complete an application as described in § 422.501.

(2) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an MA plan as defined in § 422.2.

(3) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the MA organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the MA organization to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the MA organization, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the MA organization.

(v) Insurance policies or other arrangements, secured and maintained by the MA organization and approved by CMS to insure the MA organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the organization; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(*2*) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow

compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution,

(*2*) Identify noncompliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(*3*) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

(c) *Contracting authority*. Under the authority of section 1857(c)(5) of the Act, CMS may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the bid) of at least one-third of the MA organizations offering MA plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the MA contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the MA organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005, and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 75 FR 19809, Apr. 15, 2010]

§ 422.504 Contract provisions.

The contract between the MA organization and CMS must contain the following provisions:

(a) *Agreement to comply with regulations and instructions.* The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An MA organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The MA organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in § 422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under § 422.101 and, to the extent applicable, supplemental benefits under § 422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.310 for submitting data to CMS;

(9) That it will be paid under the contract in accordance with the payment rules in subpart G of this part;

(10) To develop its annual bid, and submit all required information on premiums, benefits, and cost-sharing by not later than the first Monday in June, as provided in subpart F of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of MA plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) Address complaints received by CMS against the MAO by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the MA plan's main Web page.

(16) An MA organization's compliance with paragraphs (a)(1) through (15) and (c) of this section is material to performance of the contract.

(17) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(18) To maintain a Part C summary plan rating score of at least 3 stars. A Part C summary plan rating is calculated by taking an average of a contract's Part C performance measure scores.

(b) *Communication with CMS.* The MA organization must have the capacity to communicate with CMS electronically.

(c) *Prompt payment.* The MA organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by CMS, as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The MA organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid) of MA organizations.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the MA organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid proposal.

(v) Establish component rates of the bid for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the MA organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection, audit, or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

(iv) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the MA organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The MA organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(f) *Disclosure of information.* The MA organization agrees to submit—

(1) To CMS, certified financial information that must include the following:

(i) Such information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

(2) To CMS, all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under § 422.64 and, upon an enrollee's, request the financial disclosure information required under § 422.516.

(g) *Beneficiary financial protections.* The MA organization agrees to comply with the following requirements:

(1) Effective January 1, 2010, each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any enrollee liable for payment of any such fees;

(ii) Indemnify the enrollee for payment of any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's enrollees; and

(iii) For all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will—

(A) Accept the MA plan payment as payment in full, or

(B) Bill the appropriate State source.

(2) The MA organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the MA organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) *MA organization relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment

of any fees that are the obligation of the MA organization.

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a first tier, downstream, or related entity, in a manner consistent with the requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any first tier, downstream and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA organization; or

(B) The credentialing process will be reviewed and approved by the MA organization and the MA organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions.

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's contract with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The MA organization agrees to include in the contract such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the data it submits under § 422.310 are accurate, complete, and truthful.

(3) If such data are generated by a related entity, contractor, or subcontractor of an MA organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.254.

(m)(1) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(n) *Release of summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(1) For Part C, the following data—

(i) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(ii) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(iii) Average Part C risk score for each MA plan offered.

(iv) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(2) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

[63 FR 35099, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 as amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 72 FR 68723, Dec. 5, 2007; 73 FR 54250, Sept. 18, 2008; 74 FR 1542, Jan. 12, 2009; 75 FR 19810, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 77 FR 22168, Apr. 12, 2012]

§ 422.505 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the MA organization and CMS and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with 422.506, contracts are renewed annually only if the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 as amended at 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an MA organization.* (1) An MA organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an MA organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if—

(i) The MA organization notifies its Medicare enrollees in accordance with paragraph (a)(2)(ii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an MA organization does not renew a contract under this paragraph (a), CMS will not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(5) During the same 2-year period as specified in paragraph (a)(4) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the nonrenewing sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) The MA organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in § 422.152(d).

(ii) For any of the reasons listed in § 422.510(a), which would also permit CMS to terminate the contract.

(iii) The MA organization has committed any of the acts in § 422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(iv) The contract must be nonrenewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the MA organization by August 1 of the contract year.

(ii) To each of the MA organization's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(3) *Opportunity to develop and implement a corrective action plan.* (i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(4) *Notice of appeal rights.* CMS gives the MA organization written notice of

its right to appeal the decision not to renew in accordance with § 422.644.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002; 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007; 74 FR 1542, Jan. 12, 2009; 75 FR 19811, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011]

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the MA organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the MA organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new MA contract, the MA organization is not required to provide the notice specified in paragraph (a)(1) of this section.

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration.

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19811, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011]

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care programs, including submission of false or fraudulent data.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid data as required under § 422.310.

(7) Fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(8) Substantially fails to comply with the prompt payment requirements in § 422.520.

(9) Substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(10) Fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(11) Substantially fails to comply with the marketing requirements in subpart V of this part.

(12) Fails to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(13) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(14) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the MA organization in writing 90 days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(2) *Expedited termination of contract by CMS.* (i) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization; or

(B) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

(iii) CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

(iv) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization;

(ii) The MA organization experiences financial difficulties so severe that its

ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the MA organization informing it of its termination appeal rights in accordance with subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 52027, Sept. 1, 2005; 72 FR 68723, Dec. 5, 2007; 75 FR 19811, Apr. 15, 2010; 77 FR 22168, Apr. 12, 2012]

§ 422.512 Termination of contract by the MA organization.

(a) *Cause for termination.* The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice.* The MA organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options, original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the MA organization's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* (1) CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.≤[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002; 76 FR 21569, Apr. 15, 2011]

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the

PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an MA organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* (1) For a contract applicant or MA organization that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract or during the first 3 years of the contract, CMS may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or MA organization must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or MA organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or MA organization has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(iii) The contract applicant or MA organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(2) If an MA organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an MA contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an MA organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an MA organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the MA organization has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good

cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in § 422.500) between the MA organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the MA organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the MA organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the MA organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the MA organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information.* Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

§ 422.520 Prompt payment by MA organization.

(a) *Contract between CMS and the MA organization.* (1) The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the ''clean claims'' within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b)(1) *Contracts between MA organizations and providers and suppliers.* Contracts or other written agreements between MA organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

(2) The MA organization is obligated to pay contracted providers under the

terms of the contract between the MA organization and the provider.

(c) *Failure to comply.* If CMS determines, after giving notice and opportunity for hearing, that an MA organization has failed to make payments in accordance with paragraph (a) of this section, CMS may provide—

(1) For direct payment of the sums owed to providers, or MA private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an MA organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the MA RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

[70 FR 4738, Jan. 28, 2005]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership*—(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the MA organization's corporation into another corporation or the consolidation of the MA organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the MA organization's corporation, with the MA organization surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An MA organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The MA organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of

ownership on the surviving organization.

(2) If the MA organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the MA organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(e) *Effect of change of ownership with novation agreement.* If the MA organization submits a novation agreement that meets the requirements of § 422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The MA organization notifies CMS at least 60 days before the date of the proposed change of ownership. The MA organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The MA organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an MA organization under subpart K of this part.

(b) *Provisions of a novation agreement*—(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

§ 422.553 Effect of leasing of an MA organization's facilities.

(a) *General effect of leasing.* If an MA organization leases all or part of its facilities to another entity, the other entity does not acquire MA organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities.* (1) If an MA organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an MA organization, it must apply for and enter into a contract in accordance with subpart K of this part.

(c) *Effect of partial lease of facilities.* If the MA organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the MA organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis.* (1) Section 1852(f) of the Act provides that an MA organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an MA organization must meet concerning organization determinations and appeals.

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

(b) *Scope.* This subpart sets forth—

(1) Requirements for MA organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of MA enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an MA enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

(c) *Relation to ERISA requirements.* Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the MA organization, and if necessary, an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review.

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 68 FR 16667, Apr. 4, 2003; 70 FR 4738, Jan. 28, 2005; 75 FR 19812, Apr. 15, 2010]

§ 422.562 General provisions.

(a) *Responsibilities of the MA organization.* (1) An MA organization, with respect to each MA plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations;

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An MA organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the MA organization; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the MA organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the MA organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(4) An MA organization must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

(v) The right to request MAC review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the MA organization; and

(ii) The QIO review decision is subject only to the appeal procedures set

forth in parts 476 and 478 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4738, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 76 FR 21569, Apr. 15, 2011]

§ 422.564 Grievance procedures.

(a) *General rule.* Each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in § 422.566(b). Upon receiving a complaint, an MA organization must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process.* Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the MA organization. For quality of care issues, an enrollee may file a grievance with the MA organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* An MA organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an MA organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an MA organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

(g) *Recordkeeping.* The MA organization must have an established process to track and maintain records on all grievances received both orally and in

writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the MA organization notified the enrollee of the disposition.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

(4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) The enrollee (including his or her representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 70 FR 4739, Jan. 28, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 76 FR 21569, Apr. 15, 2011]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(b) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

(c) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny service or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item or service, in whole or in part.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010]

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the MA organization) may request that an MA organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the

determination, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The MA organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the MA organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the MA organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health

condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements of this section.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the MA organization) determined to have an appealable interest in the proceeding.

[63 FR 35107, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. A physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in § 422.582. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

[74 FR 1542, Jan. 12, 2009]

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the MA organization or CMS obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination or, upon providing notice to the enrollee, a physician who is treating an enrollee and acting on the enrollee's behalf, must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days from the date of the notice of the organization determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the MA organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination or a physician acting on behalf of an enrollee may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the MA organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

[74 FR 1542, Jan. 12, 2009]

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the MA organization) may request that an MA organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The MA organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the MA organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the MA organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.586 Opportunity to submit evidence.

The MA organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the MA organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the

enrollee (and effectuate it in accordance with § 422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration*—(1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, an MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the MA organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the MA organization

must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the MA organization's reconsideration, with the addition of the MA organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the MA organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

[65 FR 40331, June 29, 2000]

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter.

(c) If the basis for the appeal is the MA organization's refusal to provide services, CMS uses the projected value of those services to compute the amount remaining in controversy.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the MA organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal. The regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate.

[70 FR 4740, Jan. 28, 2005]

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The Board denied the party's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4740, Jan. 28, 2005]

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the MA organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization—* (1) *Requests for service.* If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar

days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision or that it has appealed the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council.* If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization.* If on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice

reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council.* If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it authorizes or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[65 FR 40331, June 29, 2000, as amended at 68 FR 50859, Aug. 22, 2003]

§ 422.620 Notifying enrollees of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of §§ 422.620 and 422.622, the term hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of §§ 422.620 and 422.622, a discharge is a formal release of an enrollee from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare Advantage enrollees, hospitals must deliver valid, written notice of an enrollee's rights as a hospital inpatient including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the enrollee's admission to the hospital.

(2) *Content of the notice.* The notice of rights must include the following information:

(i) The enrollee's rights as a hospital inpatient, including the right to benefits for inpatient services and for post hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The enrollee's right to request an immediate review, including a description of the process under § 422.622 and the availability of other appeals processes if the enrollee fails to meet the deadline for an immediate review.

(iii) The circumstances under which an enrollee will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) The enrollee's right to receive additional information in accordance with section § 422.622(e).

(v) Any other information required by CMS.

(3) *When delivery of notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If an enrollee refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the enrollee (or enrollee's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under 422.620(b) is delivered within 2 calendar days of discharge.

(d) *Physician concurrence required.* Before discharging an enrollee from the inpatient hospital level of care, the MA organization must obtain concurrence from the physician who is responsible for the enrollee's inpatient care.

[71 FR 68723, Nov. 27, 2006]

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

(a) *Enrollee's right to an immediate QIO review.* An enrollee has a right to request an immediate review by the QIO when an MA organization or hospital (acting directly or through its utilization committee), with physician concurrence determines that inpatient care is no longer necessary.

(b) *Requesting an immediate QIO review.* (1) An enrollee who wishes to exercise the right to an immediate review must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The enrollee, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The enrollee may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) An enrollee who makes a timely request for an immediate QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraph (f) of this section, as applicable.

(5) When an enrollee does not request an immediate QIO review in accordance with paragraph (b) of this section, he or she may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (f) of this section do not apply.

(c) *Burden of proof.* When an enrollee (or his or her representative, if applicable) requests an immediate review by a QIO, the burden of proof rests with the MA organization to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the MA organization should supply any and all information that a QIO requires to sustain the organization's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the enrollee's request for an immediate review under paragraph (b), the QIO must notify the MA organization and the hospital that the enrollee has filed a request for an immediate review.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 422.620(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the enrollee (or his or her representative) who requested the immediate QIO review.

(5) The QIO must provide an opportunity for the MA organization to explain why the discharge is appropriate.

(6) When the enrollee requests an immediate QIO review in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the enrollee, the hospital, the MA organization, and the physician of its determination within one calendar day after it receives all requested pertinent information.

(7) If the QIO does not receive the information needed to sustain an MA organization's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the MA organization may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues its determination, the QIO must notify the enrollee, the MA organization, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date an enrollee becomes fully liable for the services.

(iv) Information about the enrollee's right to a reconsideration of the QIO's determination as set forth in § 422.626(f), including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of the MA organization and hospital.* (1) When the QIO notifies an MA organization that an enrollee has requested an immediate QIO review, the MA organization must, directly or by delegation, deliver a detailed notice to the enrollee as soon as possible, but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation of why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy including information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the discharge determination was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon notification by the QIO of a request for an immediate review, the MA organization must supply any and all information, including a copy of the notices sent to the enrollee, as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section, that the QIO needs to decide on the determination. The MA organization must supply this information as soon as possible, but no later than noon of the day after the QIO notifies the MA organization that a request for an expedited determination has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of any information not transmitted initially in writing) and/or in writing, as determined by the QIO.

(3) In response to a request from the MA organization, the hospital must supply all information that the QIO needs to make its determination, including a copy of the notices required as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by close of business of the day the MA organization notifies the hospital of the request for information. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(4) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO by the MA organization, including written records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the documentation for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(f) *Coverage during QIO expedited review.* (1) An MA organization is financially responsible for coverage of services as provided in this paragraph, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

(2) When the MA organization determines that hospital services are not, or are no longer, covered,

(i) If the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the MA organization continues to be financially responsible for the costs of the hospital stay when an appeal is filed under paragraph (a)(1) of this section until noon of the day after the QIO notifies the enrollee of its review determination, except as provided in paragraph (b)(5) of this section. If coverage of the hospital admission was never approved by the MA organization or the admission does not constitute emergency or urgently needed care as described in §§ 422.2 and 422.112(c), the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the non-coverage determination made by the MA organization.

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

(4) If the hospital determines that inpatient hospital services are no longer necessary, the hospital may not charge the enrollee for inpatient services received before noon of the day after the QIO notifies the enrollee of its review determination.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the enrollee, physician, hospital, and MA organization except in the following circumstances:

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(g).

(2) *Right to pursue the standard appeal process.* If the enrollee is no longer an inpatient in the hospital and is dissatisfied with this determination, the enrollee may appeal to an ALJ, the MAC, or a federal court, as provided for under this subpart.

[71 FR 68723, Nov. 27, 2006, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011]

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability.* (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined.* For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the MA organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination.* Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the MA organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice.* The provider must notify the enrollee of the MA organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other MA appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid.* Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice.* An MA organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010]

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an MA organization's termination decision.* An enrollee of an MA organization has a right to a fast-track appeal of an MA organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) When an enrollee fails to make a timely request to an IRE, he or she may request an expedited reconsideration by the MA organization as described in § 422.584.

(3) If, after delivery of the termination notice, an enrollee chooses to leave a provider or discontinue receipt of covered services on or before the proposed termination date, the enrollee may not later assert fast-track IRE appeal rights under this section relative to the services or expect the services to resume, even if the enrollee requests an appeal before the discontinuation date in the termination notice.

(b) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the MA organization's decision. If the IRE's decision is delayed because the MA organization did not timely supply necessary information or records, the MA organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the MA organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an MA organization's decision to terminate services to an IRE, the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the MA organization must supply any and all information that an IRE requires to sustain the MA organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The MA organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the MA organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the MA organization and the provider that the enrollee has filed a request for a fast-

track appeal, and of the MA organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the MA organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the MA organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an MA organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the MA organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the MA organization.* (1) When an IRE notifies an MA organization that an enrollee has requested a fast-track appeal, the MA organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the MA organization, including records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the MA organization that an appeal has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An MA organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice

consistent with § 422.624(b) of this subpart.

(g) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an MA organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ, the MAC, or a Federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the MA organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the MA organization or provider.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011]

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(c) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

[63 FR 35113, June 26, 1998, as amended at 77 FR 22168, Apr. 12, 2012]

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the MA organization written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The MA organization's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by August 1 of the current contract year.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 422.662.

[72 FR 68724, Dec. 5, 2007]

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with § 422.501 and § 422.502.

(2) An MA organization whose contract has been terminated under § 422.510 of this part.

(3) An MA organization whose contract has not been renewed under § 422.506 of this part.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.* (1) During a hearing to review a contract determination as described at § 422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.501 and § 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750 of this part, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752 of this part.

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19813, Apr. 15, 2010, as amended at 77 FR 22168, Apr. 12, 2012]

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000; 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to 422.692 in instances where an MA organization or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 422.510(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68724, Dec. 5, 2007, as amended at 75 FR 19813, Apr. 15, 2010]

§ 422.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19813, Apr. 15, 2010]

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[63 FR 35113, June 26, 1998, as amended at 75 FR 19813, Apr. 15, 2010]

§ 422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§ 422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 422.682 Witness lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

[75 FR 19813, Apr. 15, 2010]

§ 422.684 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68725, Dec. 5, 2007]

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing decision in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* CMS may reopen and revise an initial determination upon its own motion.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization.

(b) CMS may impose civil money penalties as specified in 422.760.

[72 FR 68725, Dec. 5, 2007, as amended at 75 FR 19814, Apr. 15, 2010]

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

(2) Imposes on MA enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and subpart F of this part.

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of § 422.206, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with § 422.216, which requires the organization to enforce the limit on balance billing under a private fee-for service plan.

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under 422.510(a), CMS may impose the intermediate sanctions at 422.750(a)(1) and (a)(3).

(c) *Civil money penalties*—(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in 422.760 for any of the determinations at 422.510(a), except 422.510(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 422.752(a).

(ii) Determinations made pursuant to 422.510(a)(4).

[63 FR 35115, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 69 FR 78338, Dec. 30, 2004; 70 FR 4741, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010]

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanction, CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed intermediate sanction and the MA organization's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at § 422.660 through § 422.684.

(c) *Effective date and duration of sanctions*—(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

(2) *Exception.* If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions

have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

(d) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3), or terminate the contract in accordance with § 422.510.

(e) Notice to impose *civil money penalties*—(1) *CMS notice to OIG.* If CMS determines that an MA organization has failed to comply with a requirement as described in 422.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon an MA organization as specified at 422.752(c)(2).

(2) *CMS notice of civil money penalties to MA organizations.* If CMS makes a determination to impose a CMP as described in 422.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The MA organization's right to a hearing under subpart T of this part.

(vi) Information about where to file the request for hearing.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003; 70 FR 4741, Jan. 28, 2005; 72 FR 68725, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19814, Apr. 15, 2010]

§ 422.758 Collection of civil money penalties imposed by CMS.

(a) When an MA organization does not request a hearing, CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in subpart T of this part.

(b) If an MA organization requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68726, Dec. 5, 2007]

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under 422.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the MA organization;

(3) The harm which resulted or could have resulted from the conduct of MA organization;

(4) The financial condition of the MA organization;

(5) The history of prior offenses by the MA organization or principals of the MA organization; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to $25,000 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees, CMS may calculate a CMP of up to $25,000 for each MA enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by a deficiency.

(3) For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to $10,000.

(4) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under 422.512 and that the MA

organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100,000, whichever is greater.

[72 FR 68726, Dec. 5, 2007, as amended at 74 FR 1542, Jan. 12, 2009]

§ 422.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68726, Dec. 5, 2007]

§ 422.764 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

[63 FR 35115, June 26, 1998. Redesignated at 72 FR 68726, Dec. 5, 2007]

Subparts P—S [Reserved]

Subpart T—Appeal procedures for Civil Money Penalties

SOURCE: 72 FR 68726, Dec. 5, 2007, unless otherwise noted.

§ 422.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857(g) of the Act provides that, for MA organizations out of compliance with the requirements in part 422 specified remedies may be imposed instead of, or in addition to, termination of the MA organization's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on MA organizations.

(b) [Reserved]

§ 422.1002 Definitions.

As used in this subpart—

Affected party means an MA organization impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part. For this definition, ''*party*'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

MA organization has the meaning given the term in 422.2.

§ 422.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 422, subpart O.

§ 422.1006 Appeal rights.

(a) *Appeal rights of MA organizations.* (1) Any MA organization dissatisfied with an initial determination as specified in 422.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) MA organizations may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 422.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with

the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 422.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 422.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 422.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 422.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination.* CMS, as required under § 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to a hearing, and information about where to file the request for hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 422.1020 Request for hearing.

(a) *Manner and timing of request.* (1) An MA organization is entitled to a hearing as specified in § 422.1006 and may file a request for a hearing with the Departmental Appeals Board office specified in the initial determination.

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of

law with which the affected party disagrees; and

(2) Specify the basis for each contention that the finding or conclusion of law is incorrect.

§ 422.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 422.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 422.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 422.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 422.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 422.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 422.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and

stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 422.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 422.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 422.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 422.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 422.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 422.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 422.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil money penalty exists, as specified in 422.752, the administrative law judge may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 422.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 422.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 422.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 422.1016.

§ 422.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 422.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with 422.1060.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with 422.1016.

§ 422.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 422.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 422.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 422.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 422.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 422.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 422.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains

separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 422.846, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 422.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 422.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 422.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 422.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 422.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 422.1016.

§ 422.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 422.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 422.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 422.862.

(b) *Right to judicial review.* Section 422.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special Rules:* Civil Money Penalty—Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 422.1092 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.*

(1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 422.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 422.858.

Subpart V—Medicare Advantage Marketing Requirements

SOURCE: 73 FR 54220, Sept. 18, 2008, unless otherwise noted.

§ 422.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the MA organization, or any MA plan offered by the MA organization.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization.

(3) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage.

(5) May include, but are not limited to, the following:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) *Membership activities* (for example, materials on rules involving nonpayment of premiums, confirmation of enrollment or disenrollment, or nonclaim specific notification information).—

(6) *Marketing materials exclude ad hoc enrollee communications materials, meaning* informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover claims processing or other operational issues.

[73 FR 54220, Sept. 18, 2008, as amended at 75 FR 19814, Apr. 15, 2010]

§ 422.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this subpart), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The MA organization may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

[73 FR 54220, Sept. 18, 2008, as amended at 75 FR 19814, Apr. 15, 2010]

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262 of this part, CMS determines that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written description of any supplemental benefits and services;

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, MA organizations must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

[73 FR 54220, Sept. 18, 2008, as amended at 76 FR 21569, Apr. 15, 2011]

§ 422.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

§ 422.2268 Standards for MA organization marketing.

In conducting marketing activities, MA organizations may not—

(a) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered crossselling and is prohibited.

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment (48 hours in advance, when practicable).

(h) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(i) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(j) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider

groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(k) Conduct sales presentations or distribute and accept MA plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals). Other marketing materials (as defined in § 422.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which is prohibited, regardless of value.

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

[73 FR 54220, Sept. 18, 2008, as amended at 73 FR 54250, Sept. 18, 2008; 76 FR 54634, Sept. 1, 2011]

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the MA organization must:

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 422.62(b)(3)(ii)).

[73 FR 54220, Sept. 18, 2008, as amended at 73 FR 54250, Sept. 18, 2008; 76 FR 21569, Apr. 15, 2011]

§ 422.2274 Broker and agent requirements.

For purposes of this section ''compensation'' includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. ''Compensation'' does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a MA organization markets through independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a MA organization markets through any broker or agent, whether independent (that is, non-employee) or employed.

(a) Agents and brokers must be compensated as follows:

(1) An MA organization (or other entity on its behalf) may provide compensation to a broker or agent for the sale of an MA product if the following requirements are met:

(i) The compensation amount paid by plan sponsors to an independent broker or agent:

(A) For an initial enrollment of a Medicare beneficiary into an MA plan, must be at or below the fair market value (FMV) cut-off amounts published annually by CMS.

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved]

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6-year compensation cycle).

(iv) If the MA organization contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the MA organization to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (a)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.

(2) [Reserved]

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(4) Compensation may only be paid for the beneficiary's months of enrollment during a plan year (that is, January through December).

(i) Subject to paragraph (a)(4)(ii) of this section, compensation payments may be made up front for the entire current plan year or in installments throughout the year.

(ii) When a beneficiary disenrolls from a plan during the—

(A) First 3 months of enrollment, the plan must recover all compensation paid to agents and brokers.

(B) Fourth through 12th month of their enrollment (within a single plan year), the plan must recover compensation paid to agents and brokers for those months of the plan year for which the beneficiary is not enrolled.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure that all agents selling Medicare products are trained annually through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(f) A plan sponsor must report annually, as directed by CMS—

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year; and

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

[73 FR 54250, Sept. 18, 2008, as amended at 73 FR 67412, Nov. 14, 2008; 76 FR 21569, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22168, Apr. 12, 2012]

§ 422.2276 Employer group retiree marketing.

MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart A—General Provisions

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AUTHORITY: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1106. Disclosure of Information in Possession of Agency.

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 30683, May 28, 2008]

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food,

Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Pharmacist means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements

under subpart K of this part. This includes fallback prescription drug plans.

Related entity means any entity that is related to the Part D sponsor by common ownership or control and

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68731, Dec. 5, 2007; 76 FR 21570, Apr. 15, 2011]

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another

Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 423.509(a)(5) or § 422.510(a)(5) of this chapter, or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to plan members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have enrolled in the plan selected by CMS unless individuals—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS; or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the new plan and the process for accessing care under the plan and the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special enrollment period, as described in § 423.38(c)(8)(ii).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009]

§ 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions—Full-benefit dual-eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) Medical assistance under section 1902(a)(10(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

Low-income subsidy-eligible individual. For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals as set forth in this section) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low income subsidy eligible individuals*—(1) *General rule.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low income subsidy eligible individuals in another PDP if CMS determines that the further enrollment is warranted, except as specified in paragraph (c)(2) of this section.

(2) *Part D prescription drug plans that waive a de minimis premium amount.* If a Part D plan offering basic prescription drug coverage in the area where the beneficiary resides has a monthly beneficiary premium amount that exceeds the low-income subsidy amount by a de minimis amount, and the Part D plan volunteers to waive that de minimis amount in accordance with § 423.780, then CMS does not reassign low income subsidy individuals who would otherwise be enrolled under paragraph (d)(1) of this section on the basis that the monthly beneficiary premium exceeds the low-income subsidy by a de minimis amount. A Part D plan that volunteers to waive such a de minimis amount agrees to do so for each month during the contract year for which a beneficiary qualifies for 100 percent low-income premium subsidy as provided in § 423.780(f).

(d) *Automatic enrollment rules*—(1) *General rule.* Except for low income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor, as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in

a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.* (i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(4) *Enrollment in PDP plans that voluntarily waive a de minimis premium amount.* CMS may include in the process specified in paragraph (d)(1) of this section that PDPs that voluntarily waive a de minimis amount as specified in § 423.780, if CMS determines that such inclusion is warranted.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

[75 FR 19815, Apr. 15, 2010, as amended at 76 FR 21570, Apr. 15, 2011]

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period*—(1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 through 2010.* The annual coordinated election period for the following calendar year is November 15 through December 31.

(3) *For 2011 and subsequent years.* Beginning with 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772 of this part.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment period.* Beginning in 2011, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in §422.62(a)(7), may also elect a PDP during this time.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011]

§423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under §423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods*—(1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in §423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in §423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Beginning in 2011, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in §422.62(a)(7) will be effective the first day of the month following the month in which the enrollment in the PDP is made.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21570, Apr. 15, 2011]

§423.44 Involuntary disenrollment from Part D coverage.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment*—(1) Except as specified in paragraph (d)(1)(iv) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 months; and

(B) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(iv) *Reenrollment in the PDP.* If an individual is disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(v) A PDP sponsor may not disenroll an individual who had monthly premiums withheld per § 423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS.

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the PDP, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vii) *No extension of grace period.* A beneficiary's enrollment in the PDP may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(2) *Disruptive behavior*—(i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in §423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligiblity.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies,

disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* (i) The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan effective on the first day of the 13th month after the individual left the service area.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in §423.507 through §423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under §423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP*. Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(e) *Involuntary disenrollment by CMS*—(1) *General rule*. CMS will disenroll individuals who fail to pay the Part D income related monthly adjustment amount (Part D—IRMAA) specified in § 423.286(d)(4) and § 423.293(d) of this part.

(2) *Initial grace period*. For all Part D—IRMAA amounts directly billed to an enrollee in accordance with § 423.293(d)(2), the grace period ends with the last day of the third month after the billing month.

(3) *Extension of grace period for good cause and reinstatement*. When an individual is disenrolled for failing to pay the Part D—IRMAA within the initial grace period specified in paragraph (e)(2) of this section, CMS (or an entity acting on behalf of CMS) may reinstate enrollment, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(vi), pays all Part D—IRMAA arrearages, and any overdue premiums due the Part D plan sponsor within 3 calendar months after the disenrollment date.

(4) *Notice of termination*. Where CMS has disenrolled an individual in accordance with paragraph (e)(1) of this section, the Part D plan sponsor must provide notice of termination in a form and manner determined by CMS.

(5) *Effective date of disenrollment*. After a grace period and notice of termination has been provided in accordance with paragraphs (e)(2) and (4) of this section, the effective date of disenrollment is the first day following the last day of the initial grace period.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011]

§ 423.46 Late enrollment penalty.

(a) *General*. A Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any

creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) *Role of Part D plan in determination of the penalty*. Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS.

(c) *Reconsideration*. Individuals determined to be subject to a late enrollment penalty may request reconsideration of this determination, consistent with § 423.56(g) of this part. Such review will be conducted by CMS, or an independent review entity contracted by CMS, in accordance with guidance issued by CMS. Decisions made through this review are not subject to appeal, but may be reviewed and revised at the discretion of CMS.

(d) *Record retention*. Part D plan sponsors must retain all information collected concerning a creditable coverage period determination in accordance with the enrollment records retention requirements described in § 423.505(e)(1)(iii).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008; 74 FR 1543, Jan. 12, 2009]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition*. Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or

exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 403.205 of this chapter.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20505, Apr. 15, 2008; 77 FR 22168, Apr. 12, 2012]

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified-

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Contracted pharmacy network means licensed pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, and 423.600, 423.610, 423,620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case; or

(2) Coinsurance percentage under the enrollee's Part D plan.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Incurred costs means costs incurred by a Part D enrollee for—

(1)(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) Nominal cost-sharing paid by or on behalf of an enrollee, which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(iii) Under § 423.782 of this part.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

(iii) Insulin described in section 1927(k)(2)(C) of the Act.

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.

(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents; barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 1543, Jan. 12, 2009; 76 FR 21571, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 77 FR 32407, June 1, 2012]

EFFECTIVE DATE NOTE: At 77 FR 22169, Apr. 12, 2012, § 423.100 was amended by revising the definition for ''Supplemental benefits,'' effective January 1, 2013. For the convenience of the user, the revised text is set forth as follows:

§ 423.100 Definitions.

* * * * *

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

* * * * *

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan's service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area.

(c) *Types of benefits.* The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible.* An annual deductible equal to—

(i) *For 2006.* $250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit.* (i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs (d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit.* Except as provided in paragraphs (d)(4) and (d)(5) of this section, the initial coverage limit is equal to—

(i) *For 2006.* $2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program that is—

(A) Equal to the difference between the applicable gap coinsurance percentage described in paragraph (d)(4)(iv) of this section and the discount percentage determined under the Medicare coverage gap discount program; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(iii) *Generic gap coinsurance percentage.* The generic gap coinsurance percentage is equal to—

(A) For 2011, 93 percent.

(B) For years 2012 through 2019, the amount specified in this paragraph for the previous year, decreased by 7 percentage points.

(C) For 2020 and each subsequent year, 25 percent.

(iv) *Applicable gap coinsurance percentage.* The applicable gap coinsurance percentage is equal to—

(A) For 2013 and 2014, 97.5 percent.

(B) For 2015 and 2016, 95 percent.

(C) For 2017, 90 percent.

(D) For 2018, 85 percent.

(E) For 2019, 80 percent.

(F) For 2020 and subsequent years, 75 percent.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-

of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (*1*) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(*2*) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* $3,600.

(B) *For each year 2007 through 2013.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(C) *For years 2014 and 2015.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, minus 0.25 percentage point.

(D) *For each year 2016 through 2019.* The amount specified in this paragraph for the previous year, increased by the lesser of—

(*1*) The annual percentage increase specified in (d)(5)(v) of this section plus 2 percentage points; or

(*2*) The annual percentage increase specified in (d)(5)(iv) of this section.

(E) *For 2020.* The amount specified in this paragraph for 2013 increased by the annual percentage increases specified in paragraph (d)(5)(iv) of this section for 2014 through 2020, and rounded to the nearest $50.

(F) *For 2021 and subsequent years.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(v) *Additional annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organization*s. Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.* (i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*—(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for

a covered Part D drug under a Part D sponsor's benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

(h) *Valid prescription.* A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate.* Beginning January 1, 2014, a Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21571, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012]

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*—(1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010]

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access*—(1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor's service area (as defined in § 423.112(a) of this part), each

State in a regional MA-organization's service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to

whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

(x) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an Adequate Formulary. A Part D plan's formulary must—

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically

equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(v) Effective contract year 2010, a Part D Sponsor's formulary will include all Part D drugs in a category or class that CMS has identified as meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. CMS may establish certain exceptions, which may include the application of drug utilization management under certain circumstances, through a process that provides for public notice and comment, and ensures that any exception to such requirements is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents).

(vi) Exceptions to paragraph (b)(2)(v) of this section are as follows:

(A) Drug products that are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book).

(B) Utilization management processes that limit the quantity of drugs due to safety.

(C) Other drugs that CMS specifies through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents) and which permits public notice and comment.

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i) Be applicable to all of the following:

(A) New enrollees into Part D plans following the annual coordinated election period.

(B) Newly eligible Medicare enrollees from other coverage.

(C) Individuals who switch from one plan to another after the start of the contract year.

(D) Current enrollees remaining in the plan affected by formulary changes.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules).

(A) In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days and requires the Part

D sponsor to allow multiple fills to provide up to a total of 30 days of medication.

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under §423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes* (i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in §423.454), entities providing other prescription drug coverage (as described in §423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information-

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under §423.566 or exception under §423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)(i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in §423.454), entities providing other prescription drug coverage (as described in §423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described

in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* (1) A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) Beginning January 1, 2012, a part D sponsor must assign and exclusively use a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

(5)(i) A Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

(ii) A Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.

(iii) The sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(*1*) Confirm that the NPI is active and valid; or

(*2*) Correct the NPI.

(B) If the pharmacy—

(*1*) Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or

(*2*) Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

(iv) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(v) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(d) *Treatment of compounded drug products.* With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under § 423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under § 423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 2888, Jan. 16, 2009; 75 FR 19816, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21572, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012]

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs*—(1) *Out-of-network pharmacy access.* A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) *Physician's office access.* A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of §§ 423.104(d)(2)(i)(B) and 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments,

deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of §423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with §423.124(a).

(7) *Grievance, coverage determination, and appeal procedures.* All grievance, coverage determination, and appeal rights and procedures required under §423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under §423.568 or §423.570, and a uniform model form used to request a redetermination under §423.582 or §423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under §423.153(c), as well as the medication therapy management program required under §423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) *Potential for contract termination.* The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance,

coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits*. (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information*. Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(iv) Provides immediate access to the coverage determination and redetermination processes.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information*. A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the

initial coverage limit described in §423.104(d)(3) and the out-of-pocket threshold described in §423.104(d)(5)(iii).

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54222, Sept. 18, 2008; 74 FR 1544, Jan. 12, 2009; 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011]

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in any of the following cases:

(1) An MA private fee-for-service plan described in §422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy.

(3) An I/T/U network pharmacy.

(4) A network pharmacy that is located in any of the U.S. territories.

(5) A long-term care network pharmacy.

(6) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and

systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(c) Consumer satisfaction surveys of Part D plans.

(d) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

(e) Quality improvement organization (QIO) activities.

(f) Compliance deemed on the basis of accreditation.

(g) Accreditation organizations.

(h) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005; 76 FR 21573, Apr. 15, 2011]

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that address all of the following:

(1) Includes incentives to reduce costs when medically appropriate.

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(4)(i) Establishes a daily cost-sharing rate and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, and in the case of a monthly copayment, multiplies the daily cost-sharing rate by the days supply actually dispensed—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(i)(B) of this section and may be dispensed for a supply less than 30 days under applicable law;

(B) The requirements of this paragraph (b)(4)(i) do not apply to either of the following:

(*1*) Solid oral doses of antibiotics.

(*2*) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(ii) [Reserved]

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a

sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP)*—(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) *Annual comprehensive medication review with written summaries.* (*1*) The beneficiary's comprehensive medication review—

(*i*) Must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and

(*ii*) May result in a recommended medication action plan.

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet all of the following:

(i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment.

(ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment.

(iii) Are likely to incur the following annual Part D drug costs:

(A) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(B) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in § 423.104(d)(5)(iv) of this part.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for

MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21573, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012]

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) *In general.* Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—

(1) Require all pharmacies servicing long-term care facilities, as defined in § 423.100 to—

(i) Dispense solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in such facilities in no greater than 14-day increments at a time;

(ii) Permit the use of uniform dispensing techniques for Part D drugs dispensed to enrollees in long-term care facilities under paragraph (a)(1)(i) of this section as defined by each of the long-term care facilities in which such enrollees reside; and

(2) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, and on the nature and quantity of unused brand and generic drugs, as defined in § 423.4, dispensed by the pharmacy to enrollees residing in a LTC facility. Reporting on unused drugs is waived for Part D sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section—

(1) Solid oral doses of antibiotics; or

(2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

(d) *Applicability date.* The applicability date for this section is January 1, 2013. Nothing precludes a Part D sponsor and pharmacy from mutually agreeing to an earlier implementation date.

(e) *Copayments.* Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.

(f) *Unused drugs returned to the pharmacy.* The terms and conditions that must be offered by a Part D sponsor under § 423.120(a)(5) must include provisions that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law.

[76 FR 21573, Apr. 15, 2011]

§ 423.156 Consumer satisfaction surveys.

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey

vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

[75 FR 19818, Apr. 15, 2010]

§ 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media has the same meaning given this term in 45 CFR 160.103.

E-prescribing means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3) *Exemptions.* (i) Until January 1, 2012, entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. After January 1, 2012, entities transmitting prescriptions or prescription-related information must utilize the NCPSP SCRIPT standard in all instances other than temporary/transient network transmission failures.

(ii) After January 1, 2009, electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure

and communication problems that would preclude the use of the NCPDP SCRIPT Standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(iv) Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(4) In accordance with section 1860D–4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(b) *Standards.* (1) Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section:

(i) Before April 1, 2009 the standards specified in paragraphs (b)(2)(i) and (b)(3) of this section.

(ii) On or after April 1, 2009, the standards specified in paragraphs (b)(2)(ii) and (b)(3) through (b)(6) of this section.

(2) *Prescription.* (i) The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, (Version 5.0) May 12, 2004 (incorporated by reference in paragraph (c)(1)(iv) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill prescription request transaction.

(H) Refill prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(ii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill prescription request transaction.

(H) Refill prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(M) Fill status notification transaction.

(3) *Eligibility*. (i) The Accredited Standards Committee X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/005010x279 (incorporated by reference in paragraph (c)(2)(i) of this section), for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006 supporting Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, for the NCPDP Data Record in the Detail Data Record (incorporated by reference in paragraph (c)(1)(iii) of this section), for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(4) *Medication history*. The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(v) of this section) or the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section) to provide for the communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers.

(5) *Formulary and benefits*. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(6) *Provider identifier*. The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(c) *Incorporation by reference*. The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of certain publications into this section. You may inspect copies of these publications at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The publications approved for incorporation by reference and their original sources are as follows:

(1) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(i) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005.

(ii) The National Council for Prescription Drug Programs Formulary

and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(iii) National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007 and equivalent National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), August 2007 supporting Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) for the NCPDP Data Record in the Detail Data Record.

(iv) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill).

(v) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008.

(2) Accredited Standards Committee, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (301) 970–4488; and Facsimile: (703) 970–4488 or *http://www.x12.org*.

(i) Accredited Standards Committee (ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279.

(ii) [Reserved]

Authority: Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e))

[70 FR 67593, Nov. 7, 2005, as amended at 71 FR 36023, June 23, 2006; 72 FR 66405, Nov. 27, 2007; 73 FR 18941, Apr. 7, 2008; 73 FR 69938, Nov. 19, 2008; 75 FR 38030, July 1, 2010; 77 FR 29030, May 16, 2012]

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under §§ 423.120 and 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Authority.* Nothing in this section limits CMS' authority under subparts K and O of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the FEDERAL REGISTER indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under §423.165 or §423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E [Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*—(1) *General.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered ''substantially different,'' each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(3) CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011]

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(3) *Substantial differences between bids*—(i) *General.* CMS approves a bid only if it finds that the benefit package or plan costs represented by that bid are substantially different as provided under § 423.265(b)(2) of this subpart from the benefit package or plan costs represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package or plan costs represented by that bid are substantially different from any benefit package or plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor.

(4) CMS may decline to approve a bid if the Part D sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, §§ 423.120(a) and 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011]

§ 423.279 National average monthly bid amount.

(a) *Bids included.* For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) *Calculation of weighted average.* (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) *Geographic adjustment.* (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3), (d)(4), and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(4) *Increase for income-related monthly adjustment amount (Part D—IRMAA).* Beginning January 1, 2011, Medicare beneficiaries enrolled in a Medicare Part D plan must pay an income-related monthly adjustment amount in addition to the Part D premium as determined under paragraph (c) of this section and adjusted under paragraph (d) of this section, if the enrollee's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.2115.

(i) *Social Security Administration determination.* (A) SSA determines which Part D enrollees are subject to the Part D—IRMAA and the amount each enrollee will have to pay.

(B) If an individual disagrees with SSA's determination that such individual is subject to the Part D—IRMAA, or about the amount the individual must pay, an individual may file an appeal or request a new initial determination consistent with 20 CFR part 418.

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent; and the base beneficiary premium as determined under paragraph (c) of this section.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary

premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21574, Apr. 15, 2011]

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rules.* Part D sponsors must—

(1) Charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage).

(2) Permit payment of monthly Part D premiums (if any) under the timing of payments established in § 422.262(e) of this chapter; and

(3) Permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(4) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty*—(1) *Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Collection of the income-related monthly adjustment amount (Part D—IRMAA).* (1) *Collection through withholding.* Where the Social Security Administration has determined the income-related monthly adjustment amount for an individual whose income exceeds the income threshold amounts specified at 20 CFR 418.2115, the Part D—IRMAA must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board (RRB) or the Office of Personnel Management (OPM) in the manner that the Part B premium is withheld.

(2) *Collection through direct billing.* In cases where an enrollee's benefit payment check is not sufficient to have the Part D—IRMAA withheld, or if an enrollee is not receiving such benefits, the beneficiary must be billed directly for the Part D—IRMAA. The beneficiary will have the option of paying the amount through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that CMS may specify.

(3) *Failure to pay the income-related monthly adjustment amount: General rule.* CMS will terminate Part D coverage for any individual who fails to pay the Part D—IRMAA as determined

by the Social Security Administration. CMS will terminate an enrollee's Part D coverage as specified in § 423.44(e).

(e) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

(f) *Prohibition on improper billing of premiums.* Part D plan sponsors shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 1544, Jan. 12, 2009; 76 FR 21574, Apr. 15, 2011]

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply—

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

Administrative costs means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs. Administrative costs include amounts paid by the Part D sponsor to an intermediary contracting organization for covered Part D drugs dispensed to enrollees in the sponsor's Part D plan that differ from the amount paid by the intermediary contracting organization to a pharmacy or other entity that is the final dispenser of the covered Part D drugs. For example, any profit or loss retained by an intermediary contracting organization (through discounts, rebates, or other direct or indirect price concessions) when negotiating prices with dispensing entities is considered an administrative cost.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means—

(1) The subset of costs incurred under a Part D plan (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor to—

(i) A dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) under the Part D plan;

(ii) The parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464 of this part; or

(iii) An enrollee (or third party paying on behalf of the enrollee) to indemnify the enrollee when the reimbursement is associated with obtaining drugs under the Part D plan; and

(2) These costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782 of this part. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs mean those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount means the total amount of payments (from both CMS and by or on behalf of enrollees) to a Part D plan for the coverage year for all standardized bid amounts as risk

adjusted under § 423.329(b)(1) of this part, less the administrative expenses (including return on investment) assumed in the standardized bids.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19819, Apr. 15, 2010]

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in §§ 423.780 and 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans*—(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restrictions on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments, and payment-related oversight, and program integrity activities.

(1) This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(2) This restriction does not limit CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008]

§ 423.329 Determination of payments.

(a) *Subsidy payments*—(1) *Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment*—(1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount*—(1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount*—(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) of this part and negotiated and approved under § 423.272 of

this part, or by an alternative method that CMS determines.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1545, Jan. 12, 2009]

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk*—(1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments*—(1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor*—(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor*—(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information

in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations*—(1) *Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration*—(1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the final payment. For purposes of this paragraph, the date of final payment is one of the following:

(i) For risk adjustment, the date of the final reconciled payment under § 423.343(b) of this subpart.

(ii) For reinsurance, the date of the final reconciled payment under § 423.343(c) of this subpart; for low-income cost sharing subsidies, the date of the final reconciled payment under § 423.343(d) of this subpart.

(iii) For risk-sharing payments, the date of the final payments under § 423.336 of this subpart.

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008]

Subpart H [Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the etity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—-

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a substantially completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008]

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction

of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for nonlicensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited*—(1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means, prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage. For purposes of this subpart, employment-based retiree health coverage is such coverage (as defined in § 423.882) provided through a Medicare Part D plan, or for which a plan sponsor could qualify for payments under subpart R of this part.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 1882, Jan. 12, 2012]

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this part, the requirements of this part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or

seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver*—(1) *General rule for employer-sponsored group prescription drug plans that are Medicare Part D plans.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *General rule for employer-sponsored group prescription drug plans for which a sponsor could qualify for payments under subpart R of this part.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.

(3) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(4) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(3) of this section.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act,

or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under sections 1894 and 1934 of the Act, with the benefits under Part D.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 77 FR 1882, Jan. 12, 2012; 77 FR 22170, Apr. 12, 2012]

§ 423.462 Medicare secondary payer procedures.

(a) *General rule.* The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs*—(1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage*—(1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health clinics.* Rural health clinics as defined under section 1861(aa)(2) of the Act.

(viii) Other Part D plans.

(ix) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* (i) For purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii), a Part D plan must—

(A) Include the enrollee's incurred costs (as defined in § 423.100); and

(B) Exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage.

(ii) A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part

D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

(5) *Plan-to-plan liability.* In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes.* In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made and for amounts being held for payment by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

(h) *Reporting requirements.* A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011]

§ 423.466 Timeframes for coordination of benefits.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

[75 FR 19819, Apr. 15, 2010]

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this

subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 22170, Apr. 12, 2012]

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting an Notice of Intent to Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits.

(2) After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2), (3), and (4) of this section, if a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(2) In the absence of 14 months of performance history, CMS may deny an

application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part D program.

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19820, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 77 FR 22170, Apr. 12, 2012]

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265 of this part concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v) Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the Part D plan sponsor's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the Part D plan sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of the Part D plan sponsor's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the Part D plan sponsor on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the Part D plan sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each Part D plan sponsor must establish, implement and provide effective training and education for its employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(*2*) The training and education must occur at a least annually and be a part of the orientation for new employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(*3*) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and governing body, and the Part D plan sponsor's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution;

(*2*) Identify non-compliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(*3*) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) Not have terminated a contract by mutual consent under which, as a

condition of the consent, the Part D plan sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period up to 2 years per § 423.508(e) of this subpart.

(7) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction.* For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority.* CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007; 73 FR 20507, Apr. 15, 2008; 75 FR 19820, Apr. 15, 2010]

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100

and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the disclosure and reporting requirements in § 423.505(f), § 423.514, and the requirements in § 423.329(b) of this part for submitting current and prior drug claims and related information to CMS for its use in risk adjustment calculations and for the purposes of implementing § 423.505(f), (l), and (m) and § 423.329(b) of this part.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor and its delegated first tier, downstream and related entities, that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q of this part.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(19) Effective contract year 2010, include the prompt payment provisions described in § 423.520.

(20) Effective contract year 2010, provide that pharmacies located in, or having a contract with, a long-term care facility (as defined in § 423.100) must have not less than 30 days, nor more than 90 days, to submit to the Part D sponsor claims for reimbursement under the plan.

(21) Effective contract year 2009 and subsequent contract years, update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on—

(i) January 1 of each contract year; and

(ii) Not less frequently than once every 7 days after the date in paragraph (b)(21)(i) of this section.

(22) Address complaints received by CMS against the Part D sponsor by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the Part D plan's main Web page.

(23) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(24) Provide applicable beneficiaries with applicable discounts on applicable drugs in accordance with the requirements in subpart W of part 423.

(25) Maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services.

(26) Maintain a Part D summary plan rating score of at least 3 stars. A Part D summary plan rating is calculated by taking an average of a contract's Part D performance measure scores.

(c) *Communication with CMS.* The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through audit, inspection, or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the Part D sponsor to include computer and other electronic systems; and

(iv) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) The Part D plan sponsor agrees to make available to HHS, the Comptroller General, or their designees, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D plan sponsor also agrees to make available any books, contracts, records and documentation of the Part D plan sponsor, first tier, downstream and related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures,

quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3) All data elements included in all its drug claims for purposes deemed necessary and appropriate by the Secretary, including, but not limited to the following:

(i) Reporting to Congress and the public on overall statistics associated with the operation of the Medicare prescription drug program.

(ii) Conducting evaluations of the overall Medicare program, including the interaction between prescription drug coverage under Part D of Title XVIII of the Social Security Act and the services and utilization under Parts A, B, and C of title XVIII of the Act and under titles XIX and XXI of the Act, as well as other studies addressing public health questions.

(iii) Making legislative proposals to the Congress regarding Federal health care programs and related programs.

(iv) Conducting demonstration and pilot projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.

(v) Supporting care coordination and disease management programs,

(vi) Supporting quality improvement and performance measurement activities, and;

(vii) Populating personal health care records.

(4) To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The Part D plan sponsor agrees to comply with—

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D sponsor agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and

documentation of the first tier, downstream, and related entities related to CMS' contract with the Part D sponsor.

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.

(iv) A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS, or its designees, any books, contracts, records, including medical records and documentation of the Part D sponsor, relating to the Part D program, to either the sponsor to provide to CMS, or directly to CMS or its designees.

(v) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

(vi) A provision requiring prompt payment of clean claims by the Part D sponsor, consistent with § 423.520.

(vii) A provision that establishes timeframes, consistent with § 423.505(b)(20), for long-term care pharmacies to submit claims to the Part D sponsor for reimbursement under the plan.

(viii) If applicable, a provision—

(A) Establishing regular updates of any prescription drug pricing standard used by the Part D sponsor consistent with § 423.505(b)(21); and

(B) Indicating the source used by the Part D sponsor for making any such pricing updates.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Each and every contract must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment*—(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive

officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under §423.329(b)(3) (or for fallback entities, under §423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in §423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in §423.308 of this part, including data submitted to CMS regarding direct or indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in §423.336 and §423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of accuracy of data for price comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

(l) CMS may use the information collected under paragraph (f)(3) of this section. Any restriction set forth by §423.322(b) of this part must not be construed to limit the Secretary's authority to use the information collected under paragraph (f)(3).

(m)(1) CMS may release the minimum data necessary for a given purpose from the data collected under paragraph (f)(3) of this section to Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws.

(ii) CMS data sharing procedures.

(iii) Subject, in certain cases, to encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D

sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities.

(C) Plan identifier elements on the claim are encrypted or unavailable for release to external entities with the exception of HHS grantees that CMS determines meet all of the following criteria:

(*1*) The plan identifier is essential to the study.

(*2*) The study is key to the mission of the sponsoring agency.

(*3*) The study provides significant benefit to the Medicare program.

(*4*) The requestor attests that any public findings or publications will not identify plans.

(D) Beneficiary, pharmacy, and prescriber identifier elements on the claim generally are encrypted for releases to external entities, except in limited circumstances, such as to link to another data set.

(iv) For purposes of paragraph (m)(1)(iii) of this section, States and executive-branch Federal agencies are not considered to be external entities.

(2) Any restriction set forth by § 423.322(b) of this part must not be construed to limit the Secretary's authority to release the information collected under paragraph (f)(3) of this section.

(3) CMS shall make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(n)(1) CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when the sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D sponsors.

(o) *Release of summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(1) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(2) The average Part D risk score for each Part D plan offered.

(3) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(4) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(5) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 73 FR 30683, May 28, 2008; 73 FR 54251, Sept. 18, 2008; 73 FR 70599, Nov. 21, 2008; 74 FR 1545, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22170, Apr. 12, 2012]

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007]

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan and PDP options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) During the same 2-year period specified under paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or by any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(5) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(iii) The contract must be nonrenewed as to an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the Part D plan sponsor by August 1 of the contract year.

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(iii) The notice provisions in paragraph (b)(2)(ii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan

sponsor are unable to reach agreement on the bid under subpart F.

(3) *Opportunity to develop and implement a corrective action plan.* (i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D sponsor's deficiencies and reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(4) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with § 423.642(b).

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 74 FR 1546, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011]

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

(e) *Agreement to limit new Part D applications.* As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions for a period up to 2 years, absent circumstances warranting special consideration.

(f) *Prohibition against Part D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the 2-year period specified in paragraph (e) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(1) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011]

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on credible evidence, has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs,

including submission of false or fraudulent data.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(7) Substantially fails to comply with the service access requirements in § 423.120.

(8) Substantially fails to comply with either of the following:

(i) Marketing requirements in subpart V of this part.

(ii) Information dissemination requirements of § 423.128 of this part.

(9) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(10) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(11) Fails to comply with the regulatory requirements contained in this part.

(12) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part.

(13) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(B) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the violation specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination in is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

(iii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iv) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan

sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(ii) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with §423.642.

(e) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 73 FR 20507, Apr. 15, 2008; 75 FR 19822, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011; 77 FR 22170, Apr. 12, 2012]

§423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* (1) CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) During the same 2-year period specified in (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as

covered persons for the terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21575, Apr. 15, 2011]

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Validation of Part D reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting requirements for pharmacy benefits manager data.* Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following:

(1) The total number of prescriptions that were dispensed.

(2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

(3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

(4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

(5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(6) The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

(e) *Confidentiality of pharmacy benefits manager data.* Information disclosed by a Part D sponsor or PBM as specified in paragraph (d) of this section is confidential and must not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(f) *Penalties for failure to provide pharmacy benefits manager data.* The provisions of section 1927(b)(3)(C) of the Act are applicable to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under section 1927 of the Act.

(g) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(h) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(i) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

(j) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness,

and comparability in accordance with specifications developed by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19822, Apr. 15, 2010; 77 FR 22171, Apr. 12, 2012]

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

§ 423.520 Prompt payment by Part D sponsors.

(a) *Contract between CMS and the Part D sponsor.* (1) Effective contract year 2010, the contract between the Part D sponsor and CMS must provide that the Part D sponsor will issue, mail, or otherwise transmit payment with respect to all clean claims, as defined in paragraph (b) of this section, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within—

(i) 14 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 30 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Date of receipt of claim.* A claim is considered to have been received—

(i) On the date on which the claim is transferred, for an electronic claim; or

(ii) On the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner.

(b) *Clean claim.* A clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.

(c) *Procedures involving claims*—(1) *Claims determined to be clean.* A claim is deemed to be a clean claim if the Part D sponsor receiving the claim does not provide notice to the submitting network pharmacy of any deficiency in the claim within—

(i) 10 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 15 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Claims determined not to be clean*—(i) *General.* If a Part D sponsor determines that a submitted claim is not a clean claim, as defined in paragraph (b) of this section, the Part D sponsor must notify the submitting network pharmacy of such determination within the period described in paragraph (c)(1) of this section. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any remaining defect or impropriety, or of any new defect or impropriety raised by the additional information, in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section. A Part D sponsor may not provide notice of a new deficiency or impropriety in the claim that could have been identified by the sponsor in the original claim submission under this paragraph.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) or contested by the Part D sponsor within the timeframe specified in paragraph (c)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment*—(1) *General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines, a Part D sponsor is not charged interest under paragraph (e)(1) in exigent circumstances that prevent the timely processing of claims, including natural disasters and other unique and unexpected events.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants*—(1) *General.* Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

[73 FR 54252, Sept. 18, 2008, as amended at 76 FR 54634, Sept. 1, 2011]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

(g) *Sale of beneficiaries not permitted.* (1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization which will be recognized and allowed by CMS.

(2) CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a pharmacy benefit package, or one contract if the sponsor holds more than one PDP contract.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 75 FR 19822, Apr. 15, 2010; 75 FR 32860, June 10, 2010]

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and

records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

§ 423.558 Scope.

(a) This subpart sets forth the requirements relating to the following:

(1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

(2) Part D IRE with respect to reconsiderations.

(3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(b) The requirements regarding reopenings, ALJ hearings, MAC review, and Judicial review are set forth in subpart U of this chapter.

[74 FR 65363, Dec. 9, 2009]

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value of a Part D drug or drugs includes any costs the enrollee

could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009]

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) Use a single, uniform exceptions and appeals process which includes, procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128 (b)(7) and (d)(1)(iii).

(iii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iv) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. These notices must comply with the standards established in § 423.128(b)(7)(iii).

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(5) A Part D plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.1970.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.1974.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.1976.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 76 FR 21575, Apr. 15, 2011]

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 calendar days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30 calendar day timeframe by up to 14 calendar days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of

the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.566 Coverage determinations.

(a) *Responsibilities of the Part D plan sponsor.* Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician or other prescriber, on behalf of the enrollee.

(d) *Who must review coverage determinations.* If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a

State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file.

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

[75 FR 19823, Apr. 15, 2010, as amended at 76 FR 21576, Apr. 15, 2011]

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b) of this part. This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician or other prescriber on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees, prescribing physicians, or other prescribers.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician or other prescriber, provide an expedited determination if the physician or other prescriber indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(2) Give the enrollee and prescribing physician or other prescriber prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee, the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1564, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.604 and § 423.1970 through § 423.1976 or is reopened and revised under § 423.1978.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician or other prescriber under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician or other prescriber may file a request for an exception.

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's conditions—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional

supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's or other prescriber's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician or other prescriber (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician or other prescriber must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound

clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at §423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under §423.568(a) or §423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under §423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician or other prescriber continues to prescribe the drug.

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under §423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under §423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with §423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's or other prescriber's supporting statement.* Nothing in this section should be construed to mean that the physician's or other prescriber's supporting statement required for an exceptions request will result in an automatic favorable decision.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009]

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.1978) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If an enrollee or prescribing physician or other prescriber acting on behalf of an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60 calendar day period in which to file a request for a redetermination has expired, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician or other prescriber, the Part D plan sponsor must provide an expedited redetermination if the physician or other prescriber indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7 calendar day timeframe established in § 423.590(a). The 7 calendar day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7 calendar day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1547, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009]

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician or other prescriber of the conditions for submitting the evidence.

[74 FR 1548, Jan. 12, 2009]

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it

receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination*—(1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other prescriber involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(3) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of an enrollee) to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012]

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.1970;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012]

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.1972.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§§ 423.610–§ 423.634 [Reserved]

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor*—(1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*—(1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) The Part D sponsor's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the Part D plan sponsor 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 423.509(b)(2)(i) of this part, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the Part D sponsor by August 1 of the current contract year.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 75 FR 19823, Apr. 15, 2010]

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 423.651.

[72 FR 68733, Dec. 5, 2007]

§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated under § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) and (b) of this part.

(b) *Burden of proof, standard of proof, and standard of review at hearing.* (1) During a hearing to review a contract determination as described at § 423.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) *Timing of favorable decision.* Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19824, Apr. 15, 2010]

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must

be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 423.641 until a hearing decision is reached and affirmed by the Administrator following review pursuant to 423.666 in instances where a Part D sponsor or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 423.509(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010]

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19824, Apr. 15, 2010]

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19824, Apr. 15, 2010]

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Witnesses lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing

[75 FR 19824, Apr. 15, 2010]

§ 423.662 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing, may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68734, Dec. 5, 2007]

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or a Part D plan sponsor that has

received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) CMS may reopen and revise an initial determination upon its own motion.

(b) *Contract determination.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor.

(b) CMS may impose civil money penalties as specified in 423.760.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010]

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a),

CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 et seq. of the Act and subpart F of this part.

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under 423.509(a), CMS may impose the intermediate sanctions at 423.750(a)(1) and (a)(3).

(c) *Civil money penalties*—(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in 423.760, for any of the determinations at 423.509(a), except 423.509(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 423.752(a).

(ii) Determinations made pursuant to 423.509(a)(4).

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19825, Apr. 15, 2010]

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanctions, CMS—

(i) Sends a written notice to the Part D plan sponsor stating the nature and basis of the proposed intermediate sanction, and the Part D plan sponsor's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D plan sponsor 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662 of this part.

(c) *Effective date and duration of sanctions*—(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health

and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

(d) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(e) *Notice to impose civil money penalties*—(1) *CMS notice to OIG.* If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement as described in 423.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon a Part D sponsor as specified at 423.752(c)(2).

(2) *CMS notice of civil money penalties to Part D plan sponsors.* If CMS makes a determination to impose a CMP described in 423.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The Part D sponsor's right to a hearing as specified under Subpart T of this part.

(vi) Information about where to file the request for hearing.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68735, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19825, Apr. 15, 2010]

§ 423.758 Collection of civil money penalties imposed by CMS.

(a) When a Part D plan sponsor does not request a hearing CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in subpart T.

(b) If a Part D sponsor requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68735, Dec. 5, 2007]

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under 423.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the Part D sponsor;

(3) The harm which resulted or could have resulted from the conduct of the Part D sponsor;

(4) The financial condition of the Part D sponsor;

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to $25,000 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees, CMS may calculate a CMP of up to $25,000 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency .

(3) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000.

(4) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, $250 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

[72 FR 68735, Dec. 5, 2007, as amended at 74 FR 1548, Jan. 12, 2009]

§ 423.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68735, Dec. 5, 2007]

§ 423.764 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

[70 FR 4525, Jan. 28, 2005. Redesignated at 72 FR 68735, Dec. 5, 2007]

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Best available evidence means evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual's low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under

a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is defined by section 1612 of the Act) and exempts support and maintenance furnished in kind. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Individual receiving home and community-based services means a full-benefit dual-eligible individual who is receiving services under a home and community-based program authorized for a State in accordance with one of the following:

(1) Section 1115 of the Act.

(2) Section 1915(c) or (d) of the Act.

(3) State plan amendment under section 1915(i) of the Act.

(4) Services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) of the Act or section 1932 of the Act.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3)An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. It exempts the value of any life insurance policy.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54253, Sept. 18, 2008; 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.773 Requirements for eligibility.

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2)Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Beneficiary of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010]

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility*—(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) *Multiple applications.* If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.* (1) The premium subsidy amount is equal to the lesser of—

(i) Under the Part D plan selected by the beneficiary, the portion of the monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the portion of the MA monthly prescription drug beneficiary premium attributable to basic prescription drug coverage (for enrollees in MA–PD plans); or

(ii) The greater of the low-income benchmark premium amount (determined under paragraph (b)(2) of this section) for the PDP region in which the subsidy eligible individual resides or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in paragraph (b)(2)(ii) of this section, with the weight for each PDP and MA–PD plan equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA–PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

(ii) *Premium amounts.* The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA–PD plan and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) of the Act for that plan and year involved.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Waiver of late enrollment penalty for subsidy-eligible individuals.* Subsidy eligible individuals, as defined in § 423.773, are not subject to a late enrollment penalty, as defined in § 423.46.

(f) *Waiver of de minimis premium amounts.* CMS will permit a Part D plan to waive a de minimis amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the de minimis amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 18182, Apr. 3, 2008; 73 FR 20508, Apr. 15, 2008; 73 FR 54253, Sept. 18, 2008; 76 FR 21576, Apr. 15, 2011]

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA–PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed $2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for

any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

(c) When the out-of-pocket cost for a covered Part D drug under a Part D sponsor's plan benefit package is less than the maximum allowable copayment, coinsurance or deductible amounts under paragraphs (a) and (b) of this section, the Part D sponsor may only charge the lower benefit package amount.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy*. CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization*. Based on information provided by CMS under paragraph (a) of this section, or obtained under paragraph (d) of this section, the Part D sponsor offering the Part D plan in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy*. The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

(d) *Use of the best available evidence process to establish cost-sharing*. Part D sponsors must—

(1) Accept best available evidence as defined in § 423.772 of this part received from beneficiaries or other individuals acting directly on their behalf; and

(2) Update the subsidy eligible individual's LIS status. and respond to requests for assistance in securing acceptable evidence of subsidy eligibility from beneficiaries or other individuals acting directly on their behalf in accordance with the process(es) established by CMS, and within the reasonable timeframe(s) as determined by CMS.

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing*. Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries in accordance with the timeframe specified in § 423.466(a) of this part.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 75 FR 19825, Apr. 15, 2010]

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area*—(1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States

or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of bids*—(1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids*—(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity

is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) *Scope.* This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Actually paid means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

Administrative costs means costs incurred by a qualified retiree prescription drug plan that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs.

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan.

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs*, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualifying covered retiree (such as the deductible, coinsurance, or cost sharing) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§. §1003(b), for governmental plans or church plans).

Part D drug is defined in §423.100 of this part.

Part D eligible individual is defined in §423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in §423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in §411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under §423.886(a).

Standard prescription drug coverage is defined in §423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 77 FR 1883, Jan. 12, 2012]

§423.884 Requirements for qualified retiree prescription drug plans.

(a) *General.* Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with §423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and §423.888(d).

(b) *Disclosure of information.* The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health

plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*—(1) *Submitting an application.* The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information.* In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions.* To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that at the same time CMS releases Part C and Part D summary payment data in accordance with §422.504(n) and §423.505(o) CMS will also release Part D retiree drug subsidy payment data for the most recently reconciled year including the name of the eligible sponsor, the total gross aggregate dollar amount of the CMS subsidy, and the number of eligible retirees;

(iii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iv) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor.* An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing*—(i) *General rule.* An application for a given plan year must be submitted prior to the beginning of the plan year by a date specified by CMS in published guidance, unless a request for an extension has been filed and approved under procedures set forth in such guidance.

(ii) *Transition rule.* For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates.* The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information for the individuals submitted as qualifying covered retirees with a CMS database(s) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation—general.* The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription coverage (as defined at § 423.100), not taking into account the value of any discount or coverage provided during the coverage gap (as defined at § 423.100). The attestation must meet all of the following standards:

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for that plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3) The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) *Methodology*—(i) *Basis of the attestation.* The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage.* (A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.* (A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(*1*) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(*2*) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage actually provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(*2*).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap.

(D) Example: If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the sponsor has a choice of basing the attestation for the year April 1, 2007 through March 30, 2008 on either the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold amounts that apply to defined standard prescription drug coverage under Part D in CY 2007, or the amounts announced for CY 2008. However, in order to use the amounts applicable in CY 2007, the sponsor must submit the attestation within 60 days after the publication of the Part D coverage limits for CY 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the CY 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options (or for a subset of the benefit options).

(6) *Timing*—(i) *Annual submission.* The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) Submission following material change. The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's retiree prescription drug plan. For purposes of this clause, the term ''material change'' means the addition of a benefit option that does not impact the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(7) Notice of failure to continue to satisfy the actuarial equivalence standards. A sponsor must notify CMS, in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the drug coverage that impacts the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(e) *Disclosure of creditable prescription drug coverage status.* The sponsor must disclose to all of its retirees and their

spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit.* The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20508, Apr. 15, 2008; 76 FR 21576, Apr. 15, 2011]

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision.* For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data*—(i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified

by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans*—(i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section, may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross covered plan-related retiree prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS

adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009]

§ 423.890 Appeals.

(a) *Informal written reconsideration*—(1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor

of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening*—(1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and

the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Noncovered drugs are those drugs specifically excluded from the definition of Part D drug, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88⅓ percent; in 2008 is 86⅔ percent; in 2009 is 85 percent; in 2010 is 83⅓ percent; in 2011 is 81⅔ percent; in 2012 is 80 percent; in 2013 is 78⅓ percent; in 2014 is 76⅔ percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process*—(1) *Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.* (i) States may require submission of statements from financial institutions

for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information.* States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906 General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Noncovered drugs.* States may elect to provide coverage for outpatient drugs other than Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be

provided.

(2) The low-income population (income less than 150

percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the

amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a

portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment—*

(1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the monthly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D.	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	$500,000,000	CMS–64
(iv) ...	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans.	$1,600	(1) × [1 − (4)]
(vi) ...	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003.	$1,500	To be Determined
(vii) ...	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans.	90,000	CY MSIS data
(viii) ..	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans.	10,000	CY MSIS data
(ix) ...	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion).	0.4000	FEDERAL REGISTER
(xi) ...	Applicable growth factor (cumulative increase from 2003 through 2006).	50.0%	NHE projections
(xii) ...	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii) ..	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv) ..	Phased-down State contribution for the month	$8,586,000	1 / 12 × (9) × (10) × [1 + (11)] × (12) × (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment

characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

Subpart T—Appeal Procedures for Civil Money Penalties

SOURCE: 72 FR 68736, Dec. 5, 2007, unless otherwise noted.

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

(b) [Reserved]

[72 FR 68736, Dec. 5, 2007, as amended 77 FR 22171, Apr. 12, 2012]

§ 423.1002 Definitions.

As used in this subpart—

Affected party means any Part D sponsor or manufacturer (as defined in § 423.2305) impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in 423.4.

[72 FR 68736, Dec. 5, 2007, as amended 77 FR 22171, Apr. 12, 2012]

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in § 423.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 423.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 423.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 423.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 423.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 423.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 423.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS, as required under § 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, the party's right to a hearing, and information about where to file the request for a hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 423.1020 Request for hearing.

(a) *Manner and timing of request.* (1) A Part D sponsor is entitled to a hearing as specified in § 423.1006 and may file a request with the Departmental Appeals Board office specified in the initial determination.

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that a CMS finding or conclusion of law is incorrect.

§ 423.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 423.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate, designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 423.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 423.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 423.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 423.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 423.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 423.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 423.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 423.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 423.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 423.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of

this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 423.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 423.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an ALJ finds that the basis for imposing a civil money penalty exists, as specified in § 423.752, the ALJ may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 423.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 423.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 423.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of

any briefs or other written statements must be sent in accordance with § 423.1016.

§ 423.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 423.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 423.1058.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 423.1016.

§ 423.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 423.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 423.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 423.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 423.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 423.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 423.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 423.1076, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Department Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 423.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 423.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 423.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 423.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 423.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 423.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 423.1016.

§ 423.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 423.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 423.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 423.1092.

(b) *Right to judicial review.* Section 423.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty.* Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-calendar day period for seeking judicial review.

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is

binding unless a party files a civil action in a district court of the United States within the time frames specified in §423.858.

Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs, and the MAC with respect to reopenings.

(b) ALJs with respect to hearings.

(c) MAC with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings, MAC reviews, and judicial review by a Federal District Court.

§423.1970 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in §423.1972(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in §423.1972(b); and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescriptiion.

§423.1972 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in §423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with §423.2020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under §423.1970, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under §423.1970, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§423.1974 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal as provided in §423.2102.

§423.1976 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See § 423.2136 for a description of the procedures to follow in requesting judicial review.)

§ 423.1978 Reopening determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.1980 Reopenings of coverage determinations, redeterminations, reconsiderations, hearings and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

(iii) An ALJ to revise the hearing decision; or

(iv) The MAC to revise the hearing or review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ, or MAC may reopen as set forth in this section.

(3) Consistent with § 423.1978(b), the filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's, or MAC's decision on whether to reopen is binding and not subject to appeal.

(5) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for drug claims that were already reimbursed by the Part D plan sponsor is not a reopening.

(b) *Timeframes and requirements for reopening coverage determinations and redeterminations initiated by a Part D plan sponsor.* A Part D plan sponsor may reopen its coverage determination or redetermination on its own motion:

(1) Within 1 year from the date of the coverage determination or redetermination for any reason.

(2) Within 4 years from the date of the coverage determination or redetermination for good cause as defined in § 423.1986.

(3) At any time if there exists reliable evidence as defined in § 405.902 of this chapter that the coverage determination was procured by fraud or similar fault as defined in § 405.902.

(c) *Timeframe and requirements for reopening coverage determinations and redeterminations requested by an enrollee.* (1) An enrollee may request that a Part

D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

(2) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with §423.1986.

(d) *Timeframes and requirements for reopening reconsiderations, hearing decisions and reviews initiated by an IRE, ALJ, or the MAC.* (1) An IRE may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with §423.1986. If the IRE's reconsideration was procured by fraud or similar fault, then the IRE may reopen at any time.

(2) An ALJ or the MAC may reopen a hearing decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with §423.1986. If the hearing decision was procured by fraud or similar fault, then the ALJ or the MAC may reopen at any time.

(3) The MAC may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with §423.1986. If the MAC's decision was procured by fraud or similar fault, then the MAC may reopen at any time.

(e) *Timeframes and requirements for reopening reconsiderations, hearing decisions, and reviews requested by an enrollee or a Part D plan sponsor.* (1) An enrollee who received a reconsideration or a Part D plan sponsor may request that an IRE reopen its reconsideration decision within 180 calendar days from the date of the reconsideration for good cause in accordance with §423.1986.

(2) An enrollee who received an ALJ hearing decision or a Part D plan sponsor may request that an ALJ or the MAC reopen the hearing decision within 180 calendar days from the date of the hearing decision for good cause in accordance with §423.1986.

(3) An enrollee who received a MAC decision or a Part D plan sponsor may request that the MAC reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with §423.1986.

§423.1982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in §423.1980:

(1) The Part D plan sponsor, IRE, ALJ, or the MAC must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ, or the MAC must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of an enrollee or a Part D plan sponsor.* (1) The Part D plan sponsor, IRE, ALJ, or the MAC must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ, or the MAC must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

§423.1984 Effect of a revised determination or decision.

(a) *Coverage determinations.* The revision of a coverage determination is binding unless an enrollee submits a request for a redetermination that is accepted and processed in accordance with §423.580 through §423.590.

(b) *Redeterminations.* The revision of a redetermination is binding unless an enrollee submits a request for an IRE reconsideration that is accepted and processed in accordance with §423.600 through §423.604.

(c) *Reconsiderations.* The revision of a reconsideration is binding unless an enrollee submits a request for an ALJ hearing that is accepted and processed in accordance with §423.1970 through §423.1972 and §423.2000 through §423.2063.

(d) *ALJ hearing decisions.* The revision of a hearing decision is binding unless an enrollee submits a request for a

MAC review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *MAC review.* The revision of a MAC determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the coverage determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* Consistent with § 423.1978(c), a revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 423.1986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* (1) *General rule.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.*

(1) For purposes of this section, a ''review entity'' means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the MAC does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) An enrollee may request EAJR in place of an ALJ hearing or MAC review if the following conditions are met:

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a final decision, dismissal order, or remand order of the ALJ has not been issued; or

(ii) An ALJ has made a decision and the enrollee has filed a request for MAC review in accordance with § 423.2102 and a final decision, dismissal order, or remand order of the MAC has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements established annually by the Secretary.

(4) If there is more than one enrollee to the hearing or MAC review, each enrollee concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the enrollee is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or

(ii) A CMS Ruling that the enrollee considers invalid.

(3) Include a copy of the IRE reconsideration and of any ALJ hearing decision that the enrollee has received;

(4) If the IRE reconsideration or ALJ hearing decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

(5) If the IRE reconsideration or ALJ hearing decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request.* (1) Method and place for filing request. The enrollee may include an EAJR request in his or her request for an ALJ hearing or MAC review, or, if an appeal is already pending with an ALJ or the MAC, file a written EAJR request with the ALJ hearing office or MAC where the appeal is being considered. The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

(2) Time of filing request. The enrollee may file a request for EAJR—

(i) If the enrollee has requested a hearing, at any time before receipt of the notice of the ALJ's decision; or

(ii) If the enrollee has requested MAC review, at any time before receipt of notice of the MAC's decision.

(e) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance with paragraph (f) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (f) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the timeframe specified in paragraph (e)(2) of this section, then the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

(f) *Certification by the review entity.* If an enrollee meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the appeal are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation or CMS Ruling;

(4) But for the provision challenged, the enrollee would receive a favorable decision on the ultimate issue; and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(g) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (f) of this section:

(1) The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The enrollee has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal District Court.

(3) The enrollee must satisfy the requirements for venue under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under § 423.2136.

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for hearing or for MAC review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90 calendar day decision making timeframe begins on the day the request is received by the hearing office or the MAC.

§ 423.2000 Hearing before an ALJ: general rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing.

(b) A hearing may be conducted in-person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, or a representative of CMS, including the IRE, may participate in the hearing as specified in § 423.2010.

(d) The ALJ conducts a de novo review and issues a decision based on the hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the enrollee to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In that event, however, the ALJ will give the enrollee the opportunity to appear when the testimony is given, but may hold the hearing even if the enrollee decides not to appear.

(g) An ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding.

§ 423.2002 Right to an ALJ hearing.

(a) Consistent with § 423.1970(a), an enrollee may request a hearing before an ALJ if—

(1) The enrollee files a written request for an ALJ hearing within 60 calendar days after receipt of the written notice of the IRE's reconsideration; and

(2) The enrollee meets the amount in controversy requirements of § 423.1970.

(b) An enrollee may request that the hearing before an ALJ be expedited if:

(1) The appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(2) The enrollee submits a written or oral request for an expedited ALJ hearing within 60 calendar days of the date of the written notice of an IRE reconsideration determination. The request can only be submitted after the enrollee receives the written IRE reconsideration notice. The request should also explain why applying the standard timeframe may seriously jeopardize the life or health of the enrollee; and

(3) The enrollee meets the amount in controversy requirements of § 423.1970.

(c) The ALJ must document all oral requests for expedited hearings in writing and maintain the documentation in the case files.

(d) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration, unless there is evidence to the contrary.

(e) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the IRE's reconsideration.

§ 423.2004 Right to ALJ review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ if:

(1) The enrollee files a request for an ALJ review within 60 calendar days after receipt of the written notice of the IRE's dismissal.

(2) The enrollee meets the amount in controversy requirements of § 423.1970.

(3) For purposes of this section, the date of receipt of the IRE's dismissal is presumed to be 5 calendar days after the date of the written dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the IRE's dismissal.

(b) If the ALJ determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration.

(c) An ALJ's decision regarding an IRE's dismissal of a reconsideration request is binding and not subject to further review. The dismissal of a request for ALJ review of an IRE's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the MAC under § 423.2108(b).

§ 423.2008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Only an enrollee (or an enrollee's representative) may request a hearing before an ALJ.

(b) *Who are parties to the ALJ hearing.* The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the ALJ hearing.

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any.

(b) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the hearing process.

(1) For non-expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 5 calendar days of receipt of the notice of hearing.

(2) Within 5 calendar days of receipt of a request to participate in a non-expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable and the enrollee of his or her decision on the request to participate.

(3) For expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 1 calendar day of receipt of the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(4) Within 1 calendar day of receipt of a request to participate in an expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate.

(c) The ALJ has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate.

(d) Participation may include filing position papers or providing written testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(e) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing.

(f) CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the timeframe designated by the ALJ.

(g) The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

§ 423.2014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following:

(1) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(2) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(3) The appeals case number assigned to the appeal by the IRE, if any.

(4) The prescription drug in dispute.

(5) The plan name.

(6) The reasons the enrollee disagrees with the IRE's reconsideration.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(8) A statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *When and where to file.* Consistent with §§ 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration must be submitted:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration.

(2) With the entity specified in the IRE's reconsideration.

(i) If the request for hearing is timely filed with an entity other than the entity specified in the IRE's reconsideration, the deadline specified in § 423.2016 for deciding the appeal begins on the date the entity specified in the IRE's reconsideration receives the request for hearing.

(ii) If the request for hearing is filed with an entity, other than the entity specified in the IRE's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the adjudication timeframe.

(d) *Extension of time to request a hearing.* (1) Consistent with § 423.1972(b), if the request for hearing is not filed within 60 calendar days of receipt of the written IRE's reconsideration, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(4) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in §§ 405.942(b)(2) and (b)(3) of this chapter.

(5) If a request for hearing is not timely filed, the adjudication period in § 423.2016 begins the date the ALJ grants the request to extend the filing deadline.

§ 423.2016 Timeframes for deciding an Appeal before an ALJ.

(a) *Hearings.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, the ALJ must issue a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(b) *Expedited hearings.* (1) Standard for expedited hearing. The ALJ must provide an expedited hearing decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or the ALJ determines that

applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. The ALJ may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) Grant of a request. If the ALJ grants a request for expedited hearing, the ALJ must—

(i) Make the decision to grant an expedited hearing within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) Denial of a request. If the ALJ denies a request for expedited hearing, the ALJ must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that the ALJ will process the enrollee's request using the 90 calendar day timeframe for non-expedited ALJ hearings; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) A decision on a request for expedited hearing may not be appealed.

(5) Timeframe for adjudication. (i) If the ALJ accepts a request for expedited hearing, the ALJ must issue a written decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the entity specified in the IRE's reconsideration, or, if it is not timely provided, the date that the ALJ grants any extension to the filing deadline.

§ 423.2018 Submitting evidence before the ALJ hearing.

(a) *All hearings.* An enrollee may submit any written evidence that he or she wishes to have considered at the hearing.

(1) An ALJ will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination to be considered.

(b) *Non-expedited hearings.* (1) Except as provided in this paragraph, a represented enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written evidence later than 10 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 423.2016.

(3) The requirements of this subsection do not apply to unrepresented enrollees.

(c) *Expedited hearings.* (1) Except as provided in this section, an enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 2 calendar days of receiving the notice of hearing.

(2) If an enrollee submits written evidence later than 2 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 423.2016.

(d) The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

§ 423.2020 Time and place for a hearing before an ALJ.

(a) *General.* Consistent with § 423.1972(b), the ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made.* (1) The ALJ will direct that the appearance of an individual be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance.

(2) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the enrollee.

(3) The ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if—

(i) The video-teleconferencing technology is not available; or

(ii) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) The ALJ sends a notice of hearing to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee (and any potential participant from CMS, the IRE, and/or the Part D plan who has requested to participate in the hearing consistent with § 423.2010) to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing; or

(ii) Objecting to the proposed time and/or place of the hearing.

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record.

(1) As specified in § 423.2000, the ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

(e) *An enrollee's objection to time and place of hearing.* (1) If an enrollee objects to the time and place of the hearing, the enrollee must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The enrollee must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally. The ALJ must document all oral objections to the time and place of an expedited hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause. (Section 423.2052(a)(2) provides the procedures the ALJ follows when an enrollee does not respond to a notice of hearing and fails to appear at the time and place of the hearing.)

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the enrollee's contention that—

(1) The enrollee or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the enrollee's reason for requesting the change, the facts supporting the request, and the impact of the change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the enrollee.

(3) Examples of other circumstances an enrollee might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The enrollee has attempted to obtain a representative but needs additional time.

(ii) The enrollee's representative was appointed within 10 calendar days of the scheduled hearing for non-expedited hearings (or 2 calendar days for expedited hearings) and needs additional time to prepare for the hearing.

(iii) The enrollee's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to an enrollee's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for an enrollee to travel to the hearing.

(vi) The enrollee is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language).

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication deadline as specified in § 423.2016.

(i) *An enrollee's request for an in-person hearing.* (1) If an enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, the enrollee must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time or place he or she wants the hearing to be held.

(3) The request must be in writing except for an expedited hearing for which the request may be provided orally. The ALJ must document all oral objections to an expedited video-teleconferencing or telephone hearing in writing and maintain the documentation in the case files.

(4) When an enrollee's request for an in-person hearing is granted, the ALJ must issue a decision within the adjudicatory timeframe as specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Managing Field Office ALJ, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person before the ALJ.

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, unless the enrollee or other potential participant indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed or served at least 3 calendar days before the hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains a statement of the specific issues to be decided and will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(2) The notice must include an explanation of the procedures for requesting a change in the time or place of the

hearing, a reminder that, if the enrollee fails to appear at the scheduled hearing without good cause, the ALJ may dismiss the hearing request, and other information about the scheduling and conduct of the hearing.

(3) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(4) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at §423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, an amended notice is sent to him or her by certified mail or, if available, fax or e-mail. See §423.2052 for the procedures the ALJ follows in deciding if the time or place of a scheduled hearing will be changed if an enrollee does not respond to the notice of hearing).

§423.2024 Objections to the issues.

(a) If an enrollee objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing, except for expedited hearings in which the enrollee must submit written or oral notice of objection no later than 2 calendar days before the hearing. The ALJ hearing office must document all oral objections in writing and maintain the documentation in the case files.

(b) The enrollee must provide the reasons for his or her objections.

(c) The ALJ makes a decision on the objections either in writing or at the hearing.

§423.2026 Disqualification of the ALJ.

(a) An ALJ may not conduct a hearing if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ who will conduct the hearing, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing. The ALJ must document all oral objections in writing and maintain the documentation in the case files. The ALJ considers the enrollee's objections and decides whether to proceed with the hearing or withdraw.

(c) If the ALJ withdraws, another ALJ will be appointed to conduct the hearing. If the ALJ does not withdraw, the enrollee may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with §423.2100 through §423.2130. The MAC would then consider whether the hearing decision should be revised or a new hearing held before another ALJ.

§423.2030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept documents that are material to the issues consistent with §423.2018.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Reopen the hearing.* The ALJ may reopen the hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence pursuant to §423.1986. The

ALJ may decide when the evidence is presented and when the issues are discussed.

§ 423.2032 Issues before an ALJ.

(a) *General rule.* The issues before the ALJ include all the issues brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor. However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the enrollee before the hearing and may consider it an issue at the hearing.

(b) *New issues*—(1) *General.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue any time before the start of the hearing.

(2) *Content of the new issues.* The new issue may include issues resulting from the participation of CMS, the IRE, and/or the Part D plan sponsor at the ALJ level of adjudication and from any evidence and position papers submitted by CMS, the IRE, and/or the Part D plan sponsor for the first time to the ALJ.

(3) *Consideration of new issues.* The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue if its resolution—

(i) Could have a material impact on the issue or issues that are the subject of the request for hearing; and

(ii) Is permissible under the rules governing reopening of determinations and decisions as specified in § 423.1980.

(c) *Adding issues to a pending appeal.* An ALJ may not add any issue, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless it has been adjudicated at the lower appeals levels and the enrollee is notified of the new issue(s) before the start of the hearing.

§ 423.2034 When an ALJ may remand a case.

(a) *General.* (1) If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, then the ALJ may either:

(i) Remand the case to the IRE that issued the reconsideration or

(ii) Retain jurisdiction of the case and request that the CMS, the IRE, and/or the Part D plan sponsor forward the missing information to the appropriate hearing office.

(2) If the information is not information that can be provided only by CMS, the IRE, and or the Part D plan sponsor, the ALJ must retain jurisdiction of the case and obtain the information on his or her own, or directly from the enrollee.

(3) ''Can be provided only by CMS, the IRE, and/or the Part D plan sponsor'' means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. It includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor website or information in an official CMS or HHS publication.

(b) *ALJ remands a case to an IRE.*

(1) Consistent with § 423.2004(b), the ALJ will remand a case to the appropriate IRE if the ALJ determines that an IRE's dismissal of a request for reconsideration was in error.

(2) The ALJ will remand a case to the appropriate Part D IRE if the ALJ determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal.

§ 423.2036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) An enrollee has the right to appear at the hearing before the ALJ to present evidence and to state his or her position. An enrollee may appear by video-teleconferencing, telephone, or in person as determined under § 423.2020.

(2) An enrollee may also make his or her appearance by means of a representative, who may make his or her appearance by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(3) Witness testimony may be given and CMS, IRE, and Part D plan sponsor

participation may also be accomplished by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(b) *Waiver of the right to appear.* (1) An enrollee may send the ALJ a written statement indicating that he or she does not wish to appear at the hearing.

(i) For expedited hearings, an enrollee may indicate in writing or orally that he or she does not wish to appear at the hearing.

(ii) The ALJ hearing office must document all oral waivers in writing and maintain the documentation in the case files.

(2) The enrollee may subsequently withdraw his or her waiver in writing at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the enrollee agrees to an extension of the adjudication period as specified in § 423.2016, that may be necessary to schedule and hold the hearing.

(3) Even if the enrollee waives his or her right to appear at a hearing, the ALJ may require him or her to attend an oral hearing if the ALJ believes that a personal appearance and testimony by the enrollee is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* An enrollee or an enrollee's appointed representative, as defined at § 423.560, may appear before the ALJ to state the enrollee's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record.

(d) *Waiver of adjudication period.* At any time during the hearing process, the enrollee may waive the adjudication deadline specified in § 423.2016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the enrollee.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court. However, the ALJ may not consider evidence on any change in condition of an enrollee after a coverage determination. If the enrollee wishes for the evidence to be considered, the ALJ must remand the case to the Part D IRE as set forth in § 423.2034(b)(2).

(f)(1) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative, issue subpoenas for the appearance and testimony of witnesses and for the enrollee and/or the Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. An ALJ may not issue a subpoena to CMS, or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

(2) *Reviewability of an ALJ Subpoena.* A subpoena issued by an ALJ is not subject to immediate review by the MAC. The subpoena may be reviewed solely during the MAC's review specified in § 423.2102 and § 423.2110.

(3) *Exception.* To the extent a subpoena compels disclosure of a matter which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the MAC may review immediately the ruling of the ALJ on the objections to the subpoena or that portion of the subpoena as applicable.

(i) Upon notice to the ALJ that the enrollee or a non-party, as applicable, intends to seek MAC review of the ALJ's ruling on the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(ii) The proceedings are stayed for 15 calendar days or until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's subpoena, whichever comes first.

(iii) If the MAC does not take action within the 15 calendar days, then the stay is lifted and the enrollee or non-party must comply with the ALJ's subpoena.

(4) *Enforcement.* (i) If the ALJ determines that an enrollee or person other than the enrollee subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request that the Secretary seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) After submitting the enforcement request, the time period for the ALJ to issue a decision, dismissal or remand a case in response to a request for hearing is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(iii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or person other than the enrollee subject to the subpoena.

(iv) The ALJ must promptly mail a copy of the notice and related documents to the individual or entity subject to the subpoena, to the enrollee, and to any other affected person.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allow the enrollee or his or her appointed representative, as defined at § 423.560.

§ 423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision wholly favorable.* If the evidence in the hearing record supports a finding in favor of the enrollee(s) on every issue, the ALJ may issue a hearing decision without giving the enrollee(s) prior notice and without holding a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video teleconferencing, if available. The ALJ hearing office must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform the ALJ that he or she wants to appear.

(2) When a hearing is not held, the decision of the ALJ must refer to the evidence in the record on which the decision was based.

§ 423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) The ALJ hearing office must document all oral requests not to receive written notice of the conference in writing and maintain the documentation in the case files.

(e) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the enrollee consents in writing. A record of the conference is made.

(f) The ALJ issues an order stating all agreements and actions resulting from the conference. If the enrollee does not object, the agreements and actions become part of the hearing record and are binding.

§ 423.2042 The administrative record.

(a) *Creating the record.* (1) The ALJ makes a complete record of the evidence, including the hearing proceedings, if any.

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, medical

records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits.

(3) An enrollee may review the record at the hearing, or, if a hearing is not held, at any time before the ALJ's notice of decision is issued.

(4) If a request for review is filed, the complete record, including any recording of the hearing, is forwarded to the MAC.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) An enrollee may request and receive a copy of all or part of the record, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests all or part of the record from the ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the enrollee's response does not count toward the adjudication deadline.

§ 423.2044 Consolidated hearing before an ALJ.

(a) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ.

(b) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the requests for hearing are combined. In considering the enrollee's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an enrollee to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(c) The ALJ may also propose on his or her own motion to consolidate two or more cases in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing by sending written notice to the ALJ.

(1) For non-expedited hearings, any request by CMS to participate must be made within 5 calendar days of receipt of the ALJ's notice of the consolidation.

(2) For expedited hearings, any request by CMS to participate must be made within 1 calendar day of receipt of the ALJ's notice of the consolidation. Requests may be made orally or submitted by facsimile to the hearing office.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each issue. The ALJ ensures that any evidence that is common to all appeals and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

§ 423.2046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(1) For expedited hearings, the ALJ issues a written decision within the 10 calendar day adjudication timeframe under § 423.2016(b)(5).

(2) The decision must be based on evidence offered at the hearing or otherwise admitted into the record.

(3) A copy of the decision should be mailed to the enrollee at his or her last known address.

(4) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor

that issued the coverage determination.

(b) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's decision is a new coverage determination under § 423.566.

(d) *Timing of decision.* For non-expedited hearings, the ALJ issues a decision no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 90 calendar day period is extended as provided in § 423.2016. For expedited hearings, the ALJ issues a decision as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 10 calendar day period is extended as provided in § 423.2016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in a MAC remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to the enrollee at his or her last known address.

§ 423.2048 The effect of an ALJ's decision.

The decision of the ALJ is binding unless—

(a) An enrollee requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 423.2110, and the MAC issues a final decision or remand order;

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 423.1980;

(c) The expedited access to judicial review process at § 423.1990 is used;

(d) The ALJ's decision is a recommended decision directed to the MAC and the MAC issues a decision; or

(e) In a case remanded by a Federal District Court, the MAC assumes jurisdiction under the procedures in § 423.2138 and the MAC issues a decision.

§ 423.2050 Removal of a hearing request from an ALJ to the MAC.

If a request for hearing is pending before an ALJ, the MAC may assume responsibility for holding a hearing by requesting that the ALJ send the hearing request. If the MAC holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to the enrollee at his or her last known address informing him or her that the MAC has assumed responsibility for the case.

§ 423.2052 Dismissal of a request for a hearing before an ALJ.

Dismissal of a request for a hearing is in accordance with the following:

(a) *Dismissal of a request for a hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) At any time before notice of the hearing decision is mailed, if the enrollee asks to withdraw the request. This request may be submitted in writing to the ALJ or be made orally at the hearing. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request

for hearing and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(2) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed without further notice for failure to appear; or

(ii) The enrollee did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 calendar days for non-expedited hearings and 2 calendar days for expedited hearings and provide good cause for not appearing; or

(iii) The ALJ sends a notice to the enrollee asking why the enrollee did not appear; and the enrollee does not respond within 10 calendar days for non-expedited hearings; the ALJ does not receive the enrollee's response within 2 calendar days for expedited hearings or the enrollee does not provide good cause for the failure to appear. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iv) In determining whether good cause exists under paragraph (a)(2) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(3) The person requesting a hearing has no right to it under § 423.2002.

(4) The enrollee did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 423.2014(d).

(5) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not want to continue the appeal.

(6) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or the MAC has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(7) The enrollee abandons the request for hearing. An ALJ may conclude that an enrollee has abandoned a request for hearing when the ALJ hearing office attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(8) Consistent with § 423.1972(c)(1), the ALJ dismisses a hearing request if a request clearly shows that the amount in controversy is less than that required under § 423.1970.

(b) *Notice of dismissal.* The ALJ mails a written notice of the dismissal of the hearing request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the MAC vacate the dismissal action.

(c) *Discontinuation of a hearing.* Consistent with § 423.1972(c)(2), the ALJ discontinues a hearing and does not rule on the substantive issues raised in the appeal if, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.1970.

§ 423.2054 Effect of dismissal of a request for a hearing before an ALJ.

The dismissal of a request for a hearing is binding, unless it is vacated by the MAC under § 423.2108(b).

§ 423.2062 Applicability of policies not binding on the ALJ and MAC.

(a) ALJs and the MAC are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or MAC declines to follow a policy in a particular case, the ALJ or MAC decision must explain the

reasons why the policy was not followed. An ALJ or MAC decision to disregard a policy applies only to the specific coverage determination being considered and does not have precedential effect.

§ 423.2063 Applicability of laws, regulations and CMS Rulings.

(a) All laws and regulations pertaining to the Medicare programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and the MAC.

(b) CMS Rulings are published under the authority of the CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

§ 423.2100 Medicare appeals council review: general.

(a) Consistent with § 423.1974, the enrollee may request that the MAC review an ALJ's decision or dismissal.

(b) When the MAC reviews an ALJ's written decision, it undertakes a de novo review.

(c) The MAC issues a final decision, dismissal order, or remands a case no later than the end of the 90 calendar period beginning on the date the request for review is received (by the entity specified in the ALJ's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited MAC review.

(d) If an enrollee requests expedited MAC review, the MAC issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

§ 423.2102 Request for MAC review when ALJ issues decision or dismissal.

(a)(1) An enrollee to the ALJ hearing may request a MAC review if the enrollee files a written request for a MAC review within 60 calendar days after receipt of the ALJ's written decision or dismissal.

(2) An enrollee may request that MAC review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the MAC review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The MAC must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ's written decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's action.

(b) An enrollee requesting a review may ask that the time for filing a request for MAC review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The MAC must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the MAC finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards outlined at § 405.942(b)(2) and § 405.942(b)(3).

(c) An enrollee does not have the right to seek MAC review of an ALJ's remand or an ALJ's affirmation of an IRE's dismissal of a request for reconsideration.

§ 423.2106 Where a request for review may be filed.

When a request for a MAC review is filed after an ALJ has issued a written decision or dismissal, the request for review must be submitted to the entity specified in the notice of the ALJ's action. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

§ 423.2108 MAC Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision de novo. The enrollee requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence admitted into the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to the ALJ for further proceedings. Unless the MAC's review is expedited as provided in paragraph (d) of this section, the MAC must issue its action no later than 90 calendar days after receiving the request for review, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *Review of ALJ's dismissal.* When an enrollee requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) *MAC dismissal of request for review.* The MAC will dismiss a request for review when the individual or entity requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) *Expedited reviews.* (1) *Standard for expedited reviews.* The MAC must provide an expedited review if the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, enrollee's prescribing physician or other prescriber indicates, or the MAC determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. The MAC may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal.

(2) *Grant of a request.* If the MAC grants a request for expedited review, the MAC must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Issue a decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received by the entity specified in the ALJ's written notice of decision.

(3) *Denial of a request.* If the MAC denies a request for expedited review, the MAC must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 calendar days of receiving the request written notice of the denial. The written notice must inform the enrollee of the denial and explain that the MAC will process the enrollee's request using the 90 calendar day timeframe for non-expedited reviews.

(4) *Decision on a request.* A decision on a request for expedited review may not be appealed.

§ 423.2110 MAC reviews on its own motion.

(a) *General rule.* The MAC may decide on its own motion to review a decision or dismissal issued by an ALJ. CMS or the IRE may refer a case to the MAC for it to consider reviewing under this

authority any time within 60 calendar days after the ALJ's written decision or dismissal is issued.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the MAC if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the MAC take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the ALJ level; and

(ii) In CMS' or the IRE's view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.

(2) CMS' or the IRE's referral to the MAC is made in writing and must be filed with the MAC no later than 60 calendar days after the ALJ's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the MAC should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the MAC within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the MAC must send the comments to CMS or the IRE.

(c) *Standard of review.* (1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the ALJ level.* If CMS or the IRE participated or requested to participate in an appeal at the ALJ level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the ALJ proceedings.* The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(d) *MAC's action.* (1) If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request.

(3) The MAC must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The MAC may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the MAC declines to review a decision or dismissal on its own motion, the ALJ's decision or dismissal is binding.

§423.2112 Content of request for review.

(a)(1) The request for MAC review must be filed with the entity specified in the notice of the ALJ's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The MAC must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare health insurance claim number; the ALJ appeal number; the specific Part D drug(s) for which the

review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name and signature of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ action with which the enrollee requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

§ 423.2114 Dismissal of request for review.

The MAC dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request MAC review; or

(c) The enrollee died while the request for review is pending and the enrollee's estate or representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

§ 423.2116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

§ 423.2118 Obtaining evidence from the MAC.

An enrollee may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of the CD of the oral proceedings. However, the enrollee may be asked to pay the costs of providing these items. If an enrollee requests evidence from the MAC and an opportunity to comment on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

§ 423.2120 Filing briefs with the MAC.

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 423.2100. The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in MAC review.

§ 423.2122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC will consider the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. If the hearing decision decides a new issue that the enrollee was not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(3) The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination is made. The MAC will remand a case to the Part D IRE if the MAC determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination considered.

(b) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The MAC may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the MAC that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena, tolling the time period for the MAC to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement.* (1) If the MAC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the MAC to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(3) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The MAC must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

§ 423.2124 Oral argument.

An enrollee may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

§ 423.2126 Case remanded by the MAC.

(a) *When the MAC may remand a case to the ALJ.* (1) The MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in its remand order whether the ALJ will issue a decision or a recommended decision on remand.

(2) *Action by ALJ on remand.* The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(3) *Notice when case is returned with a recommended decision.* When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the enrollee at his or her last known address. The notice tells the enrollee that the case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(4) *Filing briefs with the MAC when ALJ issues recommended decision.* (i) An enrollee may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision or with the request for review for expedited appeals. An enrollee may ask the MAC for additional time to file a brief or written statement. The MAC will extend this period, as appropriate, if the enrollee shows that he or she has good cause for requesting the extension.

(ii) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(5) *Procedures before the MAC.* (i) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(ii) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

(b) *When the MAC must remand a case to the Part D IRE.* The MAC will remand a case to the appropriate Part D IRE if the MAC determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal.

§ 423.2128 Action of the MAC.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in § 423.2122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to the enrollee at his or her last known address, to CMS, to the IRE, and to the Part D plan sponsor.

§ 423.2130 Effect of the MAC's decision.

The MAC's decision is final and binding unless a Federal District Court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 423.1980. An enrollee may file an action in a Federal District Court within 60 calendar days after the date the enrollee receives written notice of the MAC's decision.

§ 423.2134 Extension of time to file action in Federal District Court.

(a) An enrollee may request that the time for filing an action in a Federal District Court be extended.

(b) The request must:

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the enrollee shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in §§ 405.942(b)(2) or (b)(3) of this chapter.

§423.2136 Judicial review.

(a) *General rule.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act and consistent with §423.1976, an enrollee may obtain a court review of a MAC decision if the amount in controversy meets the threshold requirement estimated annually by the Secretary.

(b) *Court in which to file civil action.* (1) Consistent with §423.1976(c), any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

(2) If the enrollee does not reside within any judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in §423.2130 or §423.2134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in §423.1990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff enrollee will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

§423.2138 Case remanded by a Federal District Court.

When a Federal District Court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in §423.2140 will be followed.

§423.2140 MAC Review of ALJ decision in a case remanded by a Federal District Court.

(a) *General rules.* (1) In accordance with §423.2138, when a case is remanded by a Federal District Court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that an enrollee files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *An enrollee files exceptions disagreeing with the decision of the ALJ.* (1)

If an enrollee disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC.

(2) Exceptions may be filed by submitting a written statement to the MAC setting forth the reasons for disagreeing with the decision of the ALJ.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period.

(ii) The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the MAC finds good cause under the standard established in §§ 405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the MAC considers the enrollee's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the MAC about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the MAC will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction over the case within 60 calendar days after the date of the ALJ's written decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

Subpart V—Part D Marketing Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise note.

§ 423.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(5) May include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010]

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19826, Apr. 15, 2010]

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result

in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, Part D plan sponsors must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

[73 FR 54222, Sept. 18, 2008, as amended at 76 FR 21577, Apr. 15, 2011]

§ 423.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

§ 423.2268 Standards for Part D marketing.

In conducting marketing activities, a Part D plan may not—

(a) Provide cash or other remuneration as an inducement for enrollment or otherwise.

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered crossselling and is prohibited.

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment (48 hours in advance, when practicable).

(h) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(i) Distribute marketing materials for which, before expiration of the 45-day period, the PDP Sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the PDP Sponsor, its marketing representatives, or CMS.

(j) Use providers, provider groups, or pharmacies to distribute printed information for beneficiaries to use when comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidelines.

(k) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices, pharmacies or other areas where health care is delivered to individuals, except in the case where such activities are

conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card. Other marketing materials (as defined in § 423.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which are prohibited, regardless of value.

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

[73 FR 54222, Sept. 18, 2008, as amended at 73 FR 54253, Sept. 18, 2008; 76 FR 54634, Sept. 1, 2011]

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the Part D organization must—

(a) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct direct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the sponsor has informed that State it has appointed, consistent with the appointment process provided for under State law.

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 423.38(c)(8)(i)(C)).

[73 FR 54222, Sept. 18, 2008, as amended at 73 FR 54253, Sept. 18, 2008; 76 FR 21577, Apr. 15, 2011]

§ 423.2274 Broker and agent requirements.

For purposes of this section ''compensation'' includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. ''Compensation'' does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a Part D sponsor markets through independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a Part D sponsor markets through any broker or agent, whether independent (that is, non-employee) or employed.

(a) Agents and brokers must be compensated as follows:

(1) A Part D sponsor (or other entity on its behalf) may provide compensation to a broker or agent for the sale of a Part D plan only if the following requirements are met:

(i) The compensation amount paid by plan sponsors to an independent broker or agent—

(A) For an initial enrollment of a Medicare beneficiary into a PDP must be at or below the fair market value (FMV) cut-off amounts published annually by CMS; or

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved]

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation paid (creating a 6-year compensation cycle).

(iv) If the Part D sponsor contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the Part D sponsor to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (a)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the Part D sponsor to a third party for similar services during each of the previous 2 years.

(2) [Reserved]

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(iii) When a PDP is added to an MA-only plan, a new commission would be paid for the enrollment in the PDP during the first year.

(4) Compensation may only be paid for the beneficiary's months of enrollment during a plan year (that is, January through December).

(i) Subject to paragraph (a)(4)(ii) of this section, compensation payments may be made up front for the entire current plan year or in installments throughout the year.

(ii) When a beneficiary disenrolls from a plan during the—

(A) First 3 months of enrollment, the plan must recover all compensation paid to agents and brokers.

(B) Fourth through 12th month of their enrollment (within a single plan year), the plan must recover compensation paid to agents and brokers for those months of the plan year for which the beneficiary is not enrolled.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure that all agents selling Medicare products are trained annually, through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(f) Plan sponsor must report annually, as directed by CMS the following:

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year.

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

[73 FR 54253, Sept. 18, 2008, as amended at 73 FR 67413, Nov. 14, 2008; 76 FR 21577, Apr. 15, 2011; 76 FR 54635, Sept. 1, 2011; 77 FR 22171, Apr. 12, 2012]

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Subpart W—Medicare Coverage Gap Discount Program

SOURCE: 77 FR 22172, Apr. 12, 2012, unless otherwise noted.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in §423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in §423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

EFFECTIVE DATE NOTE: At 77 FR 22172, Apr. 12, 2012, §423.2305 was added, however the definition for ''other health or prescription drug coverage'' does not become effective until Jan. 1, 2013.

§423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in §423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in §423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

(5) Collect, have available, and maintain appropriate data, including data

related to manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

(8) Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D–14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.* (1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with § 423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a 1-year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in § 423.2305) for purposes of administering the program.

§ 423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

§ 423.2325 Provision of applicable discounts.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in § 423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in § 423.100).

(iii) The amount of the applicable discount (as defined in § 423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a

labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, NDC last lot expiration dates, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2306(b)(4) of this subpart. If payment is withheld in accordance with this paragraph, the manufacturer must

notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

§ 423.2335 Beneficiary dispute resolution.

The Part D coverage determination and appeals process as described in §§ 423.558 through 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

§ 423.2340 Compliance monitoring and civil money penalties.

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing (as specified in § 423.1006).

(6) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section of 1128A of the Act) apply to CMPs under this section to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good

cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under §423.2315(c) of this subpart.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 53 FR 6634, Mar. 2, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.
1815—Payment to providers for Part A services.
1820—Conditions for designating certain hospitals as critical assess hospitals.
1833(e)—Requirement to furnish information to determine payment.
1834(a)—Payment for durable medical equipment.
1834(j)—Requirements for suppliers of medical equipment and supplies.
1835—Procedures for payment to providers for Part B services.
1842(b)(3)(B)(ii)—Assignment of Part B Medicare claims.
1842(b)(6)—Payment to entities other than the supplier.
1848—Payment for physician services.
1870(e) and (f)—Settlement of claims after death of the beneficiary.

(2) Section 424.444(c) is also based on section 216(j) of the Act.

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) *Other applicable rules.* Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 481 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 60 FR 38271, July 26, 1995; 60 FR 50442, Sept. 29, 1995; 62 FR 46035, Aug. 29, 1997; 71 FR 20775, Apr. 21, 2006; 71 FR 48409, Aug. 18, 2006]

§ 424.3 Definitions.

As used in this part, unless the context indicates otherwise—

HCPCS means Healthcare Common Procedure Coding System.

ICD–9–CM means International Classification of Diseases, Ninth Revision, Clinical Modification.

Nonparticipating hospital means a hospital that does not have in effect a provider agreement to participate in Medicare.

Participating hospital means a hospital that has in effect a provider agreement to participate in Medicare.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) *Types of services.* The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) *Sources of services.* The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) *Beneficiary of services.* Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) *Certification of need for services.* When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

(5) *Claim for payment.* The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with subpart C of this part.

(6) *Sufficient information.* The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 60 FR 38271, July 26, 1995]

§ 424.7 General limitations.

(a) *Utilization review finding on medical necessity.* When a QIO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) *Hospitals subject to PPS.* Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) *Hospitals not subject to PPS and SNFs*—(i) *Basic rule.* Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) *Exception.* Payment may be made for 1 or 2 additional days if the QIO or UR committee approves them as necessary for planning for post-discharge care.

(b) *Failure to make timely utilization review.* Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after CMS has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a QIO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Certification and Plan Requirements

§ 424.10 Purpose and scope.

(a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of

stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

Section 1814(a)(2) of the Act also permits nurse practitioners or clinical nurse specialists to certify and recertify the need for post-hospital extended care services.

(b) *Scope.* This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

[60 FR 38271, July 26, 1995]

§ 424.11 General procedures.

(a) *Responsibility of the provider.* The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

(d) *Timeliness.* (1) The succeeding sections of this subpart also specify the time frames for certifications and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations, or vary the time frame (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reason for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(e) *Limitation on authorization to sign statements.* A certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in § 424.13(c).

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

(4) A nurse practitioner or clinical nurse specialist, as defined in paragraph (e)(5) or (e)(6) of this section, in the circumstances specified in § 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by CMS that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal

advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by CMS that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

[53 FR 6634, Mar. 2, 1988, as amended at 56 FR 8845, Mar. 1, 1991; 60 FR 38272, July 26, 1995]

§ 424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) *Certification of need for hospitalization when a SNF bed is not available.* (1) A physician may certify or recertify need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(c) *Signatures*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) *Exception.* If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(d) *Timing of certifications and recertifications: Cases not subject to the prospective payment system* (PPS). (1) For cases that are not subject to PPS, certification is required no later than as of the 12th day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories.

(2) The first recertification is required no later than as of the 18th day of hospitalization.

(3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Timing of certification and recertification: Cases subject to PPS.* For cases subject to PPS, certification is required as follows:

(1) For day-outlier cases, certification is required no later than one day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with § 412.80(a)(1)(i) of this chapter, or no

later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost-outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(f) *Recertification requirement fulfilled by utilization review.* (1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent physician recertifications required for cases not subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the physician recertification would have been required. The next physician recertification would need to be made no later than the 30th day following such review; if review by the UR committee took the place of this physician recertification, the review could be performed as late as the seventh day following the 30th day.

(g) *Description of procedures.* The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all cases not subject to PPS and of PPS day outlier cases.

§ 424.14 Requirements for inpatient services of inpatient psychiatric facilities.

(a) *Content of certification and recertification: General considerations.* The content requirements differ from those for other hospitals because the care furnished in psychiatric hospitals is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient care in a psychiatric hospital only if a physician certifies and recertifies the need for services consistent with the content of paragraphs (b) or (c) of this section, as appropriate.

(b) *Content of certification.* Inpatient psychiatric services were required—

(1) For treatment that could reasonably be expected to improve the patient's condition; or

(2) For diagnostic study.

(c) *Content of recertification.* (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required—

(i) For treatment that could reasonably be expected to improve the patient's condition; or

(ii) For diagnostic study; and

(2) The hospital records show that the services furnished were—

(i) Intensive treatment services;

(ii) Admission and related services necessary for diagnostic study; or

(iii) Equivalent services.

(3) The patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel.

(d) *Timing of certification and recertification.* (1) Certification is required at the time of admission or as soon thereafter as is reasonable and practicable.

(2) The first recertification is required as of the 12th day of hospitalization. Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Other requirements.* Psychiatric hospitals must also meet the requirements set forth in § 424.13 (b), (c), (f), and (g).

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 27087, May 9, 2006; 71 FR 37504, June 30, 2006]

§ 424.15 Requirements for inpatient CAH services.

(a) *Content of certification.* Medicare Part A pays for inpatient CAH services only if a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH.

(b) *Timing of certification.* Certification is required no later than 1 day before the date on which the claim for payment for the inpatient CAH services is submitted.

[58 FR 30671, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995; 62 FR 46035, 46037, Aug. 29, 1997]

§ 424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

(a) *Basic rule.* If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for the time limits specified in § 424.13(e) for certification and recertification.

(b) *Example. (Hospital that is not a psychiatric hospital and is not subject to PPS).* For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by an SNF, or a hospital or CAH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) *Content of certification*—(1) *General requirements.* Posthospital SNF care is or was required because—

(i) The individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in an SNF or a swing-bed hospital on an inpatient basis, and the SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter; or

(ii) The individual has been correctly assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30 of this chapter.

(2) *Special requirement for certifications performed prior to July 1, 2002: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swing-bed patient to a SNF within 5 days of the availability date.* Transfer of the extended care patient to the SNF is not medically appropriate.

(b) *Timing of certification*—(1) *General rule.* The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) *Special rules for certain swing-bed hospitals.* For swing-bed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in § 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

(c) *Content of recertifications.* (1) The reasons for the continued need for posthopsital SNF care:

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) *Timing of recertifications.* (1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) *Signature.* Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A physician extender (that is, a nurse practitioner, a clinical nurse specialist, or a physician assistant as those terms are defined in section 1861(aa)(5) of the Act) who does not have a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section—

(i) *Collaboration.* (A) Collaboration means a process whereby a physician extender works with a doctor of medicine or osteopathy to deliver health care services.

(B) The services are delivered within the scope of the physician extender's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the physician extender and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

(ii) *Types of employment relationships.* (A) *Direct employment relationship.* A direct employment relationship with the facility is one in which the physician extender meets the common law definition of the facility's ''employee,'' as specified in §§ 404.1005, 404.1007, and 404.1009 of title 20 of the regulations. When a physician extender meets this definition with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(B) *Indirect employment relationship.* (*1*) When a physician extender meets the definition of a direct employment relationship in paragraph (e)(2)(ii)(A) of this section with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(*2*) An indirect employment relationship does not exist if the agreement between the entity and the facility involves only the performance of delegated physician tasks under § 483.40(e) of this chapter.

(f) *Recertification requirement fulfilled by utilization review.* A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) *Description of procedures.* The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization review is used as an alternative to the second and subsequent recertifications.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 37275, Sept. 7, 1989; 58 FR 30671, May 26, 1993; 60 FR 38272, July 26, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39600, July 31, 2001; 70 FR 45055, Aug. 4, 2005; 75 FR 73626, Nov. 29, 2010]

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of

this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1]

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter, respectively. The face-to-face encounter must be performed by the certifying physician himself or herself, by a nurse practitioner, a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, a certified nurse midwife (as defined in section 1861(gg)of the Act) as authorized by State law, a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician, or, for patients admitted to home health immediately after an acute or post-acute stay, the physician who cared for the patient in an acute or post-acute facility and who has privileges at the facility. The documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled, dated and signed by the certifying physician.

(A) If the certifying physician does not perform the face-to-face encounter himself or herself, the nonphysician practitioner or the physician who cared for the patient in an acute or post-acute facility performing the face-to-face encounter must communicate the clinical findings of that face-to-face patient encounter to such certifying physician.

(B) If a face-to-face patient encounter occurred within 90 days of the start of care but is not related to the primary reason the patient requires home health services, or the patient has not seen the certifying physician or allowed nonphysician practitioner within the 90 days prior to the start of the home health episode, the certifying physician or nonphysician practitioner must have a face to face encounter with the patient within 30 days of the start of the home health care.

(C) The face-to-face patient encounter may occur through telehealth, in compliance with Section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

(D) The physician responsible for certifying the patient for home care must document the face-to-face encounter on the certification itself, or as an addendum to the certification (as described in paragraph (a)(1)(v) of this section), that the condition for which the patient was being treated in the

[1] As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.

face-to-face patient encounter is related to the primary reason the patient requires home health services, and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in §409.42(a) and (c) respectively. The documentation must be clearly titled, dated and signed by the certifying physician.

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(c) [Reserved]

(d) *Limitation of the performance of physician certification and plan of care functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician who has a financial relationship as defined in §411.354 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(1) If a physician has a financial relationship as defined in §411.354 of this chapter, with an HHA, the physician may not certify or recertify need for home health services provided by that HHA, establish or review a plan of treatment for such services, or conduct the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act unless the financial relationship meets one of the exceptions set forth in §411.355 through §411.357 of this chapter.

(2) A Nonphysician practitioner may not perform the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act if such encounter would be prohibited under paragraph (d)(i) if the nonphysician practitioner were a physician.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991, as amended at 65 FR 41211, July 3, 2000; 66 FR 962, Jan. 4, 2001; 70 FR 70334, Nov. 21, 2005; 72 FR 51098, Sept. 5, 2007; 74 FR 58133, Nov. 10, 2009; 75 FR 70463, Nov. 17, 2010; 76 FR 9503, Feb. 18, 2011; 76 FR 68606, Nov. 4, 2011]

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following:

(1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1), (c)(4) or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech-language pathology services*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

(2) *Timing.* The initial certification must be obtained as soon as possible after the plan is established.

(3) *Signature.* (i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(4) *Recertification*—(i) *Timing.* Recertification is required at least every 90 days.

(ii) *Content.* When it is recertified, the plan or other documentation in the patient's record must indicate the continuing need for physical therapy, occupational therapy or speech-language pathology services.

(iii) *Signature.* The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan must recertify the plan by signing the medical record.

(d) [Reserved]

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—(1) *Content of certification.* (i) The individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content.* The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

(f) *Blood glucose testing.* For each blood glucose test, the physician must certify that the test is medically necessary. A physician's standing order is

not sufficient to order a series of blood glucose tests payable under the clinical laboratory fee schedule.

(g) *All other covered medical and other health services furnished by providers*—(1) *Content of certification.* The services were medically necessary,

(2) *Signature.* The certificate must be signed by a physician, nurse practioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing.* The physician, nurse practioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification.* Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, 8853, Mar. 1, 1991; 63 FR 58912, Nov. 2, 1998; 65 FR 18548, Apr. 7, 2000; 71 FR 69788, Dec. 1, 2006; 72 FR 66405, Nov. 27, 2007]

§ 424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Medicare Part B pays for CORF services only if a physician certifies, and the facility physician recertifies, the content specified in paragraphs (a) and (b)(2) of this section, as appropriate.

(a) *Certification: Content.* (1) The services were required because the individual needed skilled rehabilitation services;

(2) The services were furnished while the individual was under the care of a physician; and

(3) A written plan of treatment has been established and is reviewed periodically by a physician.

(b) *Recertification*—(1) *Timing.* Recertification is required at least every 60 days for respiratory therapy services and every 90 days for physical therapy, occupational therapy, and speech-language pathology services based on review by a facility physician or the referring physician who, when appropriate, consults with the professional personnel who furnish the services.

(2) *Content.* (i) The plan is being followed;

(ii) The patient is making progress in attaining the rehabilitation goals; and,

(iii) The treatment is not having any harmful effect on the patient.

[53 FR 6634, Mar. 2, 1988, as amended at 72 FR 66405, Nov. 27, 2007]

Subpart C—Claims for Payment

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by an MA organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP), or as part of a demonstration. Therefore, claims must be filed by hospitals seeking IME payment under §412.105(g) of this chapter, and/or direct GME payment under §413.76(c) of this chapter, and/or nursing or allied health education payment under §413.87 of this chapter associated with inpatient services furnished on a prepaid capitation basis by an MA organization. Hospitals that must report patient data for purposes of the DSH payment adjustment under §412.106 of this chapter for inpatient services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with an HMO/CMP, or as part of a demonstration, are required to file claims by submitting no pay bills for such inpatients. Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

[77 FR 53682, Aug. 31, 2012]

§ 424.32 Basic requirements for all claims.

(a) A claim must meet the following requirements:

(1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions.

(2) A claim for physician services, clinical psychologist services, or clinical social worker services must include appropriate diagnostic coding for those services using ICD–9–CM.

(3) A claim must be signed by the beneficiary or on behalf of the beneficiary (in accordance with § 424.36).

(4) A claim must be filed within the time limits specified in § 424.44.

(5) All Part B claims for services furnished to SNF residents (whether filed by the SNF or by another entity) must include the SNF's Medicare provider number and appropriate HCPCS coding.

(b) The prescribed forms for claims are the following:

CMS–1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

CMS–1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

CMS–1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

CMS–1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) *Where claims forms are available.* Excluding forms CMS–1450 and CMS–1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The CMS–1450 and CMS–1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from CMS or any Social Security branch or district office, or from Medicare intermediaries or carriers. The CMS–1490S is also available at local Social Security Offices.

(d) *Submission of electronic claims*—(1) *Definitions.* For purposes of this paragraph, the following terms have the following meanings:

(i) *Claim* means a transaction defined at 45 CFR 162.1101(a).

(ii) *Electronic claim* means a claim that is submitted via electronic media. A claim submitted via direct data entry is considered to be an electronic claim.

(iii) *Direct data entry* is defined at 45 CFR 162.103.

(iv) *Electronic media* is defined at 45 CFR 160.103.

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for initial processing, including claims sent to Medicare for the first time for secondary payment purposes. Initial Medicare claim excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider or supplier other than a provider of services.

(vii) *Provider of services* means a provider of services as defined in section 1861(u) of the Act.

(viii) *Small provider of services or small supplier* means—

(A) A provider of services with fewer than 25 full-time equivalent employees; or

(B) A physician, practitioner, facility, or supplier with fewer than 10 full-time equivalent employees.

(2) *Submission of electronic claims required.* Except for claims to which paragraph (d)(3) or (d)(4) of this section applies, an initial Medicare claim may be paid only if submitted as an electronic claim for processing by the Medicare fiscal intermediary or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

(3) *Exceptions to requirement to submit electronic claims.* The requirement of paragraph (d)(2) of this section is waived for any initial Medicare claim when—

(i) There is no method available for the submission of an electronic claim. This exception includes claims submitted by Medicare beneficiaries and situations in which the standard adopted by the Secretary at 45 FR 162.1102 does not support all of the information necessary for payment of the claim. The Secretary may identify situations coming within this exception in guidance.

(ii) The entity submitting the claim is a small provider of services or small supplier.

(4) *Unusual cases.* The Secretary may waive the requirement of paragraph (d)(2) of this section in unusual cases as

the Secretary finds appropriate. Unusual cases are deemed to exist in the following situations:

(i) The submission of dental claims.

(ii) There is a service interruption in the mode of submitting the electronic claim that is outside the control of the entity submitting the claim, for the period of the interruption.

(iii) The entity submitting the claim submits fewer than 10 claims to Medicare per month, on average.

(iv) The entity submitting the claim only furnishes services outside of the U.S. territory.

(v) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

(5) *Effective date.* This paragraph (d) is effective October 16, 2003, and applies to claims submitted on or after October 16, 2003.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39601, July 31, 2001; 68 FR 48813, Aug. 15, 2003; 70 FR 71020, Nov. 25, 2005; 71 FR 48143, Aug. 18, 2006; 72 FR 66405, Nov. 27, 2007]

§ 424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless CMS instructions waive this requirement.

§ 424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) *Basic rule.* A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a ''report of services'', as specified in paragraphs (b) and (c) of this section.

(b) *Itemized bill from the hospital or supplier.* The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.

(3) The date each service was furnished.

(4) A listing of the services in sufficient detail to permit determination of payment under the fee schedule for physicians' services; for itemized bills from physicians, appropriate diagnostic coding using ICD–9–CM must be used.

(5) The charges for each service.

(c) *Report of services furnished by a supplier.* For Medicare Part B services furnished by a supplier, the beneficiary claims may include the ''Report of Services'' portion of the appropriate claims form, completed by the supplier in accordance with CMS instructions, in lieu of an itemized bill.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 59 FR 26740, May 24, 1994]

§ 424.36 Signature requirements.

(a) *General rule.* The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraphs (b), (c), or (d) of this section apply. For purposes of this section, ''the claim'' includes the actual claim form or such other form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

(b) *Who may sign when the beneficiary is incapable.* If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on his or her behalf by one of the following:

(1) The beneficiary's legal guardian.

(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.

(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.

(4) A representative of an agency or institution that did not furnish the services for which payment is claimed but furnished other care, services, or assistance to the beneficiary.

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b)(1), (2), (3), or (4) of this section after making reasonable efforts to locate and obtain the signature of one of the individuals specified in paragraph (b)(1), (2), (3), or (4) of this section.

(6) An ambulance provider or supplier with respect to emergency or nonemergency ambulance transport services, if the following conditions and documentation requirements are met.

(i) None of the individuals listed in paragraph (b)(1), (2), (3), or (4) of this section was available or willing to sign the claim on behalf of the beneficiary at the time the service was provided;

(ii) The ambulance provider or supplier maintains in its files the following information and documentation for a period of at least four years from the date of service:

(A) A contemporaneous statement, signed by an ambulance employee present during the trip to the receiving facility, that, at the time the service was provided, the beneficiary was physically or mentally incapable of signing the claim and that none of the individuals listed in paragraph (b)(1), (2), (3), or (4) of this section were available or willing to sign the claim on behalf of the beneficiary, and

(B) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary, and

(C) Either of the following:

(*1*) A signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility; or

(*2*) The requested information from a representative of the hospital or facility using a secondary form of verification obtained at a later date, but prior to submitting the claim to Medicare for payment. Secondary forms of verification include a copy of any of the following:

(*i*) The signed patient care/trip report;

(*ii*) The facility or hospital registration/admission sheet;

(*iii*) The patient medical record;

(*iv*) The facility or hospital log; or

(*v*) Other internal facility or hospital records.

(c) *Who may sign if the beneficiary was not present for the service.* If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* If good cause is shown, CMS may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988; 72 FR 66406, Nov. 27, 2007; 73 FR 2432, Jan. 15, 2008; 73 FR 66938, Nov. 19, 2008]

§ 424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) *Beneficiary incapable.* When a party specified in § 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—

(1) Describes his or her relationship to the beneficiary; and

(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) *Beneficiary not present for services.* When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment

statement under § 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: ''Patient not physically present for test.'')

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.40 Request for payment effective for more than one claim.

(a) *Basic procedure.* A separate request for payment statement prescribed by CMS and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) *Claims filed by a provider or nonparticipating hospital*—(1) *Inpatient services.* A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) *Home health services and outpatient physical therapy or speech pathology services.* A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) *Signed statement in the provider record*—(1) *Services to inpatients.* A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) *Services to outpatients: Providers and renal dialysis facilities.* A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics and Federally qualified health centers.* A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

§ 424.44 Time limits for filing claims.

(a) *Time limits.* (1) Except as provided in paragraphs (b) and (e) of this section, for services furnished on or after January 1, 2010, the claim must be filed no later than the close of the period ending 1 calendar year after the date of service.

(2) Except as provided in paragraphs (b) and (e) of this section and except for services furnished during the last 3 months of 2009, for services furnished before January 1, 2010, the claim must be filed—

(i) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(ii) On or before December 31st of the second following year for services that were furnished during the last 3 months of the calendar year.

(3) For services furnished during the last 3 months of CY 2009 all claims

must be filed no later than December 31, 2010.

(b) *Exceptions to time limits.* Exceptions to the time limits for filing claims include the following:

(1) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority.

(2) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(3) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) A State Medicaid agency recovered the Medicaid payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(4) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was enrolled in a Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization.

(ii) The beneficiary was subsequently disenrolled from the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization effective retroactively to or before the date of the furnished service.

(iii) The Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(5) *Extension of time.* (i) If CMS or one of its contractors determines that a failure to meet the deadline specified in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification that the error or misrepresentation referenced in paragraph (b)(1) of this section was corrected. No extension of time will be granted for paragraph (b)(1) when the request for that exception is made to CMS or one of its contractors more than 4 years after the date of service.

(ii) If CMS or one of its contractors determines that both of the conditions are met in paragraph (b)(2) of this section but that all of the conditions in paragraph (b)(3) are not satisfied, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(3) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the State Medicaid

agency recovered the Medicaid payment for the furnished service from the provider or supplier.

(iv) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(4) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from the provider or supplier.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

(d) *Outpatient diabetes self-management training.* CMS makes payment in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date CMS approves the entity to furnish the services under part 410, subpart H of this chapter.

(e) As specified in §§ 424.520 and 424.521 of this subpart, there are restrictions on the ability of the following newly-enrolled suppliers to submit claims for items or services furnished prior to the effective date of their Medicare billing privileges:

(1) Physician or nonphysician practitioner organizations.

(2) Physicians.

(3) Nonphysician practitioners.

(4) Independent diagnostic testing facilities.

[53 FR 6634, Mar. 2, 1988, as amended at 65 FR 83153, Dec. 29, 2000; 73 FR 69939, Nov. 19, 2008; 75 FR 73627, Nov. 29, 2010]

Subpart D—To Whom Payment Is Ordinarily Made

§ 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

§ 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

§ 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

§ 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if

the hospital does not have in effect an election to claim payment in accordance with subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

§ 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

§ 424.55 Payment to the supplier.

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount approved by the carrier as the basis for determining the Medicare Part B payment (the reasonable charge or the lesser of the fee schedule amount and the actual charge).

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the Medicare approved amount.

(ii) To collect only the difference between the Medicare approved amount and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under § 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount.

(3) Not to charge the beneficiary when Medicare paid for services determined to be ''not reasonable or necessary'' if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

(c) *Exception.* In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

[53 FR 6634, Mar. 2, 1988, as amended at 63 FR 20130, Apr. 23, 1998; 69 FR 66426, Nov. 15, 2004]

§ 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment.* If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier.* Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(c) *Payment to the beneficiary.* Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) *Examples.*

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $325 on which partial payment of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) *Definitions.* As used in this section, the following definitions apply:

Accredited DMEPOS suppliers means suppliers that have been accredited by a recognized independent accreditation organization approved by CMS in accordance with the requirements at § 424.58.

Affiliate means a person or organization that is related to another person or organization through a compensation arrangement or ownership.

Assessment means a sum certain that CMS or the Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act or as specified in this chapter.

Attended facility-based polysomnogram means a comprehensive diagnostic sleep test including at least electroencephalography, electrooculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.

Authorized surety means a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

Civil money penalty (CMP) means a sum that CMS has the authority, as implemented by 42 CFR 402.1(c); or OIG has the authority, under section 1128A of the Act or 42 CFR part 1003, to impose on a supplier as a penalty.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under § 424.58.

Continuous positive airway pressure (CPAP) device means a machine that introduces air into the breathing passages at pressures high enough to overcome obstructions in the airway in order to improve airflow. The airway pressure delivered into the upper airway is continuous during both inspiration and expiration.

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraphs (c) and (d) of this section.

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges.

(ii) Suspension or revocation of a license to provide health care by any State licensing authority.

(iii) Revocation for failure to meet DMEPOS quality standards.

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation, or re-enrollment.

(v) An exclusion or debarment from participation in a Federal or State health care program.

Government-operated supplier is a DMEPOS supplier owned or operated by a Federal, State, or Tribal entity.

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

National Supplier Clearinghouse (NSC) is the contractor that is responsible for the enrollment and re-enrollment process for DMEPOS suppliers.

Penal sum is the maximum obligation of the surety if a loss occurs.

Rider means a notice issued by a surety that a change in the bond has occurred or will occur.

Sleep test means an attended or unattended diagnostic test for a sleep disorder whether performed in or out of a sleep laboratory. The 'provider of the sleep test' is the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test.

Sufficient evidence means documents CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier.

Surety bond means a bond issued by one or more sureties under 31 U.S.C. 9304 through 9308 and 31 CFR parts 223, 224, and 225.

Unpaid claim means an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible, plus accrued interest that is effective 90 days after the date of the notice sent to the DMEPOS supplier of the overpayment. If a written agreement for payment, acceptable to CMS, is made, an *unpaid claim* also means a Medicare overpayment for which the DMEPOS supplier is responsible, plus accrued interest after the DME supplier's default on the arrangement.

(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

(3) CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.

(4) A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)

(5) The supplier has furnished to CMS all information or documentation required to process the claim.

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

(i) Federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled.

(ii) *State licensure and regulatory requirements.* If a State requires licensure to furnish certain items or services, a DMEPOS supplier—

(A) Must be licensed to provide the item or service; and

(B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

(2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);

(3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;

(4) Fills orders, frabicates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal

Government Executive Branch procurement or nonprocurement program or activity;

(5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in §414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in §414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. An appropriate site must meet all of the following:

(i) Must meet the following criteria:

(A)(*1*) Except for orthotic and prosthetic personnel described in paragraph (c)(7)(i)(A)(*2*) of this section, maintains a practice location that is at least 200 square feet beginning—

(*i*) September 27, 2010 for a prospective DMEPOS supplier;

(*ii*) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010 and before September 27, 2013; or

(*iii*) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

(*2*) Orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice do not have to meet the practice location requirements in paragraph (c)(7)(i)(A)(*1*) of this section if the orthotic and prosthetic personnel are—

(*i*) State-licensed; or

(*ii*) Practicing in a State that does not offer State licensure for orthotic and prosthetic personnel.

(B) Is in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)

(C) Is accessible and staffed during posted hours of operation.

(D) Maintains a permanent visible sign in plain view and posts hours of operation. If the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier.

(E) Except for business records that are stored in centralized location as described in paragraph (c)(7)(ii) of this section, is in a location that contains space for storing business records (including the supplier's delivery, maintenance, and beneficiary communication records).

(F) Is in a location that contains space for retaining the necessary ordering and referring documentation specified in §424.516(f).

(ii) May be the centralized location for all of the business records and the ordering and referring documentation of a multisite supplier.

(iii) May be a ''closed door'' business, such as a pharmacy or supplier providing services only to beneficiaries residing in a nursing home, that complies with all applicable Federal, State, and local laws and regulations. ''Closed door'' businesses must comply with all the requirements in this paragraph.

(8) Permits CMS, the NSC, or agents of CMS or the NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section.

(9) Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.

(i) Cellular phones, beepers, or pagers must not be used as the primary business telephone.

(ii) Calls must not be exclusively forwarded from the primary business telephone listed under the name of the

business to a cellular phone, beeper, or pager.

(iii) Answering machines, answering services, facsimile machines or combination of these options must not be used exclusively as the primary business telephone during posted operating hours.

(10) Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) Must comply with the disclosure provisions in § 420.206 of this subchapter;

(18) Must not convey or reassign a supplier number;

(19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);

(20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

(26) Must meet the surety bond requirements specified in paragraph (d) of this section.

(27) Must obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure.)

(28) Is required to maintain ordering and referring documentation consistent with the provisions found in § 424.516(f)

(29)(i) Except as specified in paragraph (c)(29)(ii) of this section, is prohibited from sharing a practice location with any other Medicare supplier or provider.

(ii) The prohibition specified in paragraph (c)(29)(i) of this section is not applicable at a practice location that meets one of the following:

(A) Where a physician whose services are defined in section 1848(j)(3) of the Act or a nonphysician practitioner, as described in section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(B) Where a physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(C) Where a DMEPOS supplier is colocated with and owned by an enrolled Medicare provider (as described in § 489.2(b) of this chapter). The DMEPOS supplier—

(1) Must operate as a separate unit; and

(2) Meet all other DMEPOS supplier standards.

(30)(i) Except as specified in paragraph (c)(30)(ii) of this section, is open to the public a minimum of 30 hours per week.

(ii) The provision of paragraph (c)(30)(i) of this section is not applicable at a practice location where a—

(A) Physician whose services are defined in section 1848(j)(3) of the Act furnishes items to his or her own patient(s) as part of his or her professional service;

(B) A physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act furnishes items to his or her own patient(s) as part of his or her professional service; or

(C) DMEPOS supplier is working with custom made orthotics and prosthetics.

(d) *Failure to meet standards.* CMS will revoke a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. (The revocation is effective 15 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.)

(e) *Revalidation of billing privileges.* A supplier must revalidate its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last revalidation.)

(f) *Payment prohibition.* No Medicare payment will be made to the supplier

of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.

[65 FR 60377, Oct. 11, 2000, as amended at 71 FR 48409, Aug. 18, 2006; 73 FR 69939, Nov. 19, 2008; 75 FR 52648, Aug. 27, 2010; 76 FR 5962, Feb. 2, 2011; 77 FR 14994, Mar. 14, 2012]

EDITORIAL NOTE: At 74 FR 198, Jan. 2, 2009, § 424.57 was amended by redesignating paragraphs (d) and (e) as paragraphs (e) and (f), adding a new paragraph (d) and in newly redesignated paragraph (e), by removing the cross-reference, ''paragraphs (b) and (c)'' and adding the cross-reference ''paragraphs (b), (c), and (d)'' however, these amendments could not be incorporated due to inaccurate amendatory instruction. For the convenience of the user, the added text is set forth as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(d) *Surety bonds requirements*—(1) *Effective date of surety bond requirements.* (i) *DMEPOS suppliers seeking enrollment or with a change in ownership.* Except as provided in paragraph (d)(15) of this section, beginning May 4, 2009, DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS must meet the requirements of paragraph (d) of this section for each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges.

(ii) *Existing DMEPOS suppliers.* Except as provided in paragraph (d)(15) of this section, beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d) of this section for each assigned NPI to which Medicare has granted billing privileges.

(2) *Minimum requirements for a DMEPOS supplier.* (i) A supplier enrolling in the Medicare program, making a change in ownership, or responding to a revalidation or reenrollment request must submit to the NSC a surety bond from an authorized surety of $50,000 and if required by the NSC an elevated bond amount as described in paragraph (d)(3) of this section with its paper or electronic Medicare enrollment application (CMS–855S, OMB number 0938–0685). The term of the initial surety bond must be effective on the date that the application is submitted to the NSC.

(ii) A supplier that seeks to become an enrolled DMEPOS supplier through a purchase or transfer of assets or ownership interest must submit to the NSC a surety bond from an authorized surety of $50,000 and if required by the NSC an elevated bond amount as described in paragraph (d)(3) of this section that is effective from the date of the purchase or transfer in order to exercise billing privileges as of that date. If the bond is effective at a later date, the effective date of the new DMEPOS supplier billing privileges is the effective date of the surety bond as validated by the NSC.

(iii) A DMEPOS supplier enrolling a new practice location must submit to the NSC a new surety bond from an authorized surety or an amendment or rider to the existing bond, showing that the new practice location is covered by an additional base surety bond of $50,000 or, as necessary, an elevated surety bond amount as described in paragraph (d)(3) of this section.

(3) *Elevated surety bond amounts.* (i) If required, a DMEPOS supplier must obtain and maintain a base surety bond in the amount of $50,000 as specified in paragraph (d)(2) of this section and an elevated surety bond in the amount prescribed by the NSC as described in paragraph (d)(3)(ii) of this section.

(ii) The NSC prescribes an elevated surety bond amount of $50,000 per occurrence of an adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment, as defined in paragraph (a) of this section.

(4) *Type and terms of the surety bond.* (i) *Type of bond.* A DMEPOS supplier must submit a bond that is continuous.

(ii) *Minimum requirements of liability coverage.* (A) The terms of the bond submitted by a DMEPOS supplier for the purpose of complying with this section must meet the minimum requirements of liability coverage ($50,000) and surety and DMEPOS supplier responsibility as set forth in this section.

(B) CMS requires a supplier to submit a bond that on its face reflects the requirements of this section. CMS revokes or denies a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of paragraph (d) of this section.

(5) *Specific surety bond requirements.* (i) The bond must guarantee that the surety will, within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, CMPs, or assessments, pay CMS a total of up to the full penal amount of the bond in the following amounts:

(A) The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.

(B) The amount of any unpaid claims, CMPs, or assessments imposed by CMS or

OIG on the DMEPOS supplier, plus accrued interest.

(ii) The bond must provide the following: The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

(iii) If the DMEPOS supplier fails to furnish a bond meeting the requirements of paragraph (d) of this section, fails to submit a rider when required, or if the DMEPOS supplier's billing privileges are revoked, the last bond or rider submitted by the DMEPOS supplier remains in effect until the last day of the surety bond coverage period and the surety remains liable for unpaid claims, CMPs, or assessments that—

(A) CMS or the OIG imposes or asserts against the DMEPOS supplier based on overpayments or other events that took place during the term of the bond or rider; and

(B) Were imposed or assessed by CMS or the OIG during the 2 years following the date that the DMEPOS supplier failed to submit a bond or required rider, or the date the DMEPOS supplier's billing privileges were terminated, whichever is later.

(6) *Cancellation of a bond and lapse of surety bond coverage.* (i) A DMEPOS supplier may cancel its surety bond and must provide written notice at least 30 days before the effective date of the cancellation to the NSC and the surety.

(ii) Cancellation of a surety bond is grounds for revocation of the DMEPOS supplier's Medicare billing privileges unless the DMEPOS supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.

(iii) If CMS receives notification of a lapse in bond coverage from the surety, the DMEPOS supplier's billing privileges are revoked. During this lapse, Medicare does not pay for items or services furnished during the gap in coverage, and the DMEPOS supplier is held liable for the items or services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for the items or services).

(iv) The surety must immediately notify the NSC if there is a lapse in the surety's coverage of the DMEPOS supplier's coverage.

(7) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by CMS or by CMS contractors.

(8) *Required surety information on the surety bond.* The bond must provide the surety's name, street address or post office box number, city, state, and zip code.

(9) *Change of surety.* A DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the NSC at least 30 days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods. If a gap in coverage exists, the NSC revokes the supplier's billing privileges and does not pay for any items or services furnished by the DMEPOS supplier during the period for which no bond coverage was available. If a DMEPOS supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond. The previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.

(10) *Parties to the surety bond.* The surety bond must name the DMEPOS supplier as Principal, CMS as Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety.

(11) *Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond.* (i) CMS revokes the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions. Notwithstanding paragraph (e) of this section, the revocation is effective the date the bond lapsed and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier.

(ii) CMS denies billing privileges to a supplier if the supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified with this subpart and CMS instructions.

(12) *Evidence of DMEPOS supplier's compliance.* CMS may at any time require a DMEPOS supplier to show compliance with the requirements of paragraph (d) of this section.

(13) *Effect of subsequent DMEPOS supplier payment.* If a surety has paid an amount to CMS on the basis of liability incurred under a bond and CMS subsequently collects from the DMEPOS supplier, in whole or in part, on the unpaid claim, CMPs, or assessment that was the basis for the surety's liability, CMS reimburses the surety the amount that it collected from the DMEPOS supplier, up to the amount paid by the surety to CMS, provided the surety has no other liability to CMS under the bond.

(14) *Effect of review reversing determination.* If a surety has paid CMS on the basis of liability incurred under a surety bond and to the extent the DMEPOS supplier that obtained the bond is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS refunds the DMEPOS supplier the amount the DMEPOS supplier paid to CMS to the extent that the

amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

(15) *Exception to the surety bond requirement*—(i) *Qualifying entities and requirements.* (A) Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DME supplier has provided CMS with a comparable surety bond under State law.

(B) State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics are provided an exception to the surety bond requirement if—

(*1*) The business is solely-owned and operated by the orthotic and prosthetic personnel, and

(*2*) The business is only billing for orthotic, prosthetics, and supplies.

(C) Physicians and nonphysician practitioners as defined in section 1842(b)(18) of the Act are provided an exception to the surety bond requirement when items are furnished only to the physician or nonphysician practitioner's own patients as part of his or her physician service.

(D) Physical and occupational therapists in private practice are provided an exception to the surety bond requirement if—

(*1*) The business is solely-owned and operated by the physical or occupational therapist;

(*2*) The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and

(*3*) The business is only billing for orthotics, prosthetics, and supplies.

(ii) *Loss of a DMEPOS supplier exception.* A DMEPOS supplier that no longer qualifies for an exception as described in paragraph (d)(15)(i) of this section must submit a surety bond to the NSC in accordance with requirements of paragraph (d) of this section within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

§ 424.58 Accreditation.

(a) *Scope and purpose.* This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the DMEPOS quality standards for suppliers of DMEPOS and other items or services. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the DMEPOS quality standards under section 1834(a)(20) of the Act before being awarded a contract.

(b) *Application and reapplication procedures for accreditation organizations.* (1) An independent accreditation organization applying for approval or re-approval of authority to survey suppliers for compliance with the DMEPOS quality standards is required to furnish the following to CMS:

(i) A list of the types of DMEPOS supplies, and a list of products and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements, and dispute resolution processes and policies when there is a negative survey finding or decision.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the

independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiii) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that the accreditation organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(2) *Validation survey.* CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted—

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) *Discovery of a deficiency.* If CMS discovers that a DMEPOS supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) *Authorization.* A supplier selected for a validation survey must authorize the—

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) *Refusal to cooperate with survey.* If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b)(4) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its supplier billing number revoked.

(6) *Validation survey findings.* If a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.

(c) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written format (either electronic or hard copy) and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any supplier of DMEPOS and other items and services against which the CMS-approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised cross walk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS's notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all of the CMS-approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation survey.* CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS-approved accreditation organization's survey of a supplier, or observe a CMS-approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS-approved accreditation organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, irrespective of the rate of disparity, there are widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements.

(3) *Notice of intent to withdraw approval.* CMS provides the organization written notice of its intent to withdraw approval if an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not

meeting the requirements of this section.

(4) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other items and services are meeting the DMEPOS quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(e) *Reconsideration.* (1) An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization meet the applicable supplier quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(2) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(3) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(4) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(5) In response to a request for reconsideration, CMS provides the accreditation organization the opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

(6) CMS provides written notice of the time and place of the informal hearing at least 10 calendar days before the scheduled date.

(7) The informal reconsideration hearing is open to CMS and the organization requesting the reconsideration, including authorized representatives; technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and legal counsel.

(i) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(ii) Testimony and other evidence may be accepted by the hearing officer even though it is inadmissible under the rules of court procedures.

(iii) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(9) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision is final.

[71 FR 48409, Aug. 18, 2006]

Subpart E—To Whom Payment is Made in Special Situations

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

(b) The provisions applicable to payment for services excluded as custodial care or services not reasonable and necessary are set forth in §§ 405.332 through 405.336 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.62 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.* (1) The beneficiary has received covered services for which he could receive direct payment under § 424.53.

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this section. If none of those relatives survive. Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on a CMS-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must

also submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed ''Report of Services'' section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence.

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 424.64 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope.* This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation.* (1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made.* In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier.* Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a CMS-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services.* If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a CMS-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment.* Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 424.36) to receive the Part B payment

for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.

(5) Submits any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid for by the entity.* An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for which it will pay and claim reimbursement.

[53 FR 28388, July 28, 1988; 53 FR 40231, Oct. 14, 1988]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis.* This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope.* This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that CMS may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

As used in this subpart, unless the context indicates otherwise—

Court of competent jurisdiction means a court that has jurisdiction over the subject matter and the parties before it.

Facility means a hospital or other institution that furnishes health care services to inpatients.

Entity means a person, group, or facility that is enrolled in the Medicare program.

Power of attorney means any written documents by which a principal authorizes an agent to—

(1) Receive, in the agent's name, any payments due the principal;

(2) Negotiate checks payable to the principal; or

(3) Receive, in any other manner, direct payment of amounts due the principal.

[53 FR 6634, Mar. 2, 1988, as amended at 69 FR 66426, Nov. 15, 2004]

§ 424.73 Prohibition of assignment of claims by providers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a provider to any other person under assignment, or power of attorney, or any other direct payment arrangement.

(b) *Exceptions to the prohibition*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by the provider.

(2) *Payment under assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, the order of a court of competent jurisdiction if the assignment meets the conditions set forth in § 424.90.

(3) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

(i) The agent receives the payment under an agency agreement with the provider;

(ii) The agent's compensation is not related in any way to the dollar amounts billed or collected;

(iii) The agent's compensation is not dependent upon the actual collection of payment;

(iv) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and

(v) The agent, in receiving the payment, acts only on behalf of the provider.

Payment to an agent will always be made in the name of the provider.

§ 424.74 Termination of provider agreement.

CMS may terminate a provider agreement, in accordance with § 489.53(a)(1) of this chapter, if the provider—

(a) Executes or continues a power of attorney, or enters into or continues any other arrangement, that authorizes or permits payment contrary to the provisions of this subpart; or

(b) Fails to furnish, upon request by CMS or the intermediary, evidence necessary to establish compliance with the requirements of this subpart.

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter), or any other applicable Medicare laws, rules, or regulations.

(b) *Exceptions to the basic rule*—(1) *Payment to employer.* Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services.

(2) *Payment to an entity under a contractual arrangement.* Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

(3) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under a reassignment by the supplier.

(4) *Payment under a reassignment established by court order.* Medicare may pay under a reassignment established by, or in accordance with, the order of a court competent jurisdiction, if the reassignment meets the conditions set forth in § 424.90.

(5) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the supplier, or to the employer, facility, or system specified in paragraphs (b) (1), (2) and (3) of this section, if the conditions of § 424.73(b)(3) for payment to a provider's agent are met by the agent of the supplier or of the employer, facility, or system. Payment to an agent will always be made in the name of the supplier or the employer, facility, or system.

(c) *Rules applicable to an employer or entity.* An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) *Reassignment to an entity under an employer-employee relationship or under a contractual arrangement: Conditions and limitations*—(1) *Liability of the parties.* An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) *Access to records.* The supplier who furnishes the service has unrestricted access to claims submitted by an entity for services provided by that supplier. This paragraph applies irrespective of whether the supplier is an employee or whether the service is provided under a contractual arrangement. If an entity refuses to provide, upon request, the billing information

to the supplier performing the service, the entity's right to receive reassigned benefits may be revoked under § 424.82(c)(3).

(3) *Reassignment of the technical or professional component of a diagnostic test.* If a physician or other supplier bills for the technical or professional component of a diagnostic test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) following a reassignment from a physician or other supplier who performed the technical or professional component, the amount payable to the billing physician or other supplier may be subject to the limits specified in § 414.50 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 4027, Jan. 27, 1989; 69 FR 66426, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66406, Nov. 27, 2007]

§ 424.82 Revocation of right to receive assigned benefits.

(a) *Scope.* This section sets forth the conditions and procedures for revocation of the right of a supplier or other party to receive Medicare payments.

(b) *Definition.* As used in this section, *other party* means an employer, facility, or health care delivery system to which Medicare may make payment under § 424.80(b) (1), (2), or (3).

(c) *Basis for revocation.* CMS may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by CMS or the carrier—

(1) Violates the terms of assignment in § 424.55(b).

(2) Continues collection efforts or fails to refund moneys incorrectly collected, in violation of the terms of assignment in § 424.55(b).

(3) Executes or continues in effect a reassignment or power of attorney or any other arrangement that seeks to obtain payment contrary to the provisions of § 424.80; or

(4) Fails to furnish evidence necessary to establish its compliance with the requirements of § 424.80.

(d) *Proposed revocation: Notice and opportunity for review.* If CMS proposes to revoke the right to payment in accordance with paragraph (c) of this section, it will send the supplier or other party a written notice that—

(1) States the reasons for the proposed revocation; and

(2) Provides an opportunity for the supplier or other party to submit written argument and evidence against the proposed revocation. CMS usually allows 15 days from the date on the notice, but may extend or reduce the time as circumstances require.

(e) *Actual revocation: Timing, notice, and opportunity for hearing*—(1) *Timing.* CMS determines whether to revoke after considering any written argument or evidence submitted by the supplier or other party or, if none is submitted, at the expiration of the period specified in the notice of proposed revocation.

(2) *Notice and opportunity for hearing.* The notice of revocation specifies—

(i) The reasons for the revocation;

(ii) That the revocation is effective as of the date on the notice;

(iii) That the supplier or other party may, within 60 days from the date on the notice (or a longer period if the notice so specifies), request an administrative hearing and may be represented by counsel or other qualified representative.

(iv) That the carrier will withhold payment on any claims submitted by the supplier or other party until the period for requesting a hearing expires or, if a hearing is requested, until the hearing officer issues a decision;

(v) That if the hearing decision reverses the revocation, the carrier will pay the supplier's or other party's claims; and

(vi) That if a hearing is not requested or the hearing decision upholds the revocation, payment will be made to the beneficiary or to another person or agency authorized to receive payment on his or her behalf.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.83 Hearings on revocation of right to receive assigned benefits.

If the supplier or other party requests a hearing under § 424.82(e)(2)—

(a) The hearing is conducted—

(1) By a CMS hearing official who was not involved in the decision to revoke; and

(2) In accordance with the procedures set forth in §§ 405.824 through 405.833 (but excepting § 405.832(d)) and 405.860 through 405.872 of this chapter. In applying those procedures, ''CMS'' is substituted for ''carrier''; and ''hearing official'', for ''hearing officer''.

(b) As soon as practicable after the close of the hearing, the official who conducted it issues a hearing decision that—

(1) Is based on all the evidence presented at the hearing and included in the hearing record; and

(2) Contains findings of fact and a statement of reasons.

§ 424.84 Final determination on revocation of right to receive assigned benefits.

(a) *Basis of final determination*—(1) *Final determination without a hearing.* If the supplier or other party does not request a hearing, CMS's revocation determination becomes final at the end of the period specified in the notice of revocation.

(2) *Final determination following a hearing.* If there is a hearing, the hearing decision constitutes CMS's final determination.

(b) *Notice of final determination.* CMS sends the supplier or other party a written notice of the final determination and, if there was a hearing, includes a copy of the hearing decision.

(c) *Application of the final determination*—(1) A final determination not to revoke is the final administrative decision by CMS on the matter.

(2) A final determination to revoke remains in effect until CMS finds that the reason for the revocation has been removed and that there is reasonable assurance that it will not recur.

(d) *Effect of revocation when supplier or other party has a financial interest in another entity.* Revocation of the party's right to accept assignment also applies to any corporation, partnership, or other entity in which the party, directly or indirectly, has or acquires all or all but a nominal part of the financial interest.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.86 Prohibition of assignment of claims by beneficiaries.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a beneficiary under § 424.53 to any other person under assignment, power of attorney, or any other direct payment arrangement.

(b) *Exceptions*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by a beneficiary (or by the beneficiary's legal guardian or representative payee).

(2) *Payment under an assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, a court order if the assignment meets the conditions set forth in § 424.90.

§ 424.90 Court ordered assignments: Conditions and limitations.

(a) *Conditions for acceptance.* An assignment or reassignment established by or in accordance with a court order is effective for Medicare payments only if—

(1) Someone files a certified copy of the court order and of the executed assignment or reassignment (if it was necessary to execute one) with the intermediary or carrier responsible for processing the claim; and

(2) The assignment or reassignment—

(i) Applies to all Medicare benefits payable to a particular person or entity during a specified or indefinite time period; or

(ii) Specifies a particular amount of money, payable to a particular person or entity by a particular intermediary or carrier.

(b) *Retention of authority to reduce interim payments to providers.* A court-ordered assignment does not preclude the intermediary or carrier from reducing interim payments, as set forth in § 413.64(i) of this chapter, if the provider or assignee is in imminent danger of insolvency or bankruptcy.

(c) *Liability of the parties.* The party that receives payments under a court-ordered assignment or reassignment that meets the conditions of paragraph (a) of this section and the party that would have received payment if the court order had not been issued are jointly and severally responsible for any Medicare overpayment to the former.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

§ 424.100 Scope.

This subpart sets forth procedures and criteria that are followed in determining whether Medicare will pay for emergency services furnished by a hospital that is located in the United States and does not have in effect a provider agreement, that is, an agreement to participate in Medicare.

§ 424.101 Definitions.

As used in this subpart, unless the context indicates otherwise—

Emergency services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Hospital means a facility that—

(1) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(2) Is not primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care, as described in section 1861(j)(1)(A) of the Act;

(3) Provides 24-hour nursing service in accordance with section 1861(e)(5) of the Act; and

(4) Is licensed, or is approved as meeting the standards for licensing, by the State or local licensing agency.

Reasonable charges means customary charges insofar as they are reasonable.

§ 424.102 Situations that do not constitute an emergency.

Without additional evidence of a threat to life or health, the following situations do not in themselves indicate a need for emergency services:

(a) Lack of care at home.

(b) Lack of transportation to a participating hospital.

(c) Death of the patient in the hospital.

§ 424.103 Conditions for payment for emergency services.

Medicare pays for emergency services furnished to a beneficiary by a nonparticipating hospital or under arrangements made by such a hospital if the conditions of this section are met.

(a) *General requirements.* (1) The services are of the type that Medicare would pay for if they were furnished by a participating hospital.

(2) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with § 424.104.

(3) The need for emergency services arose while the beneficiary was not an inpatient in a hospital.

(4) In the case of inpatient hospital services, the services are furnished during a period in which the beneficiary could not be safely discharged or transferred to a participating hospital or other institution.

(5) The determination that the hospital was the most accessible hospital available and equipped to furnish the services is made in accordance with § 424.106.

(b) *Medical information requirements.* A physician (or, if appropriate, the hospital) submits medical information that—

(1) Describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital;

(2) Establishes that all the conditions in paragraph (a) of this section are met; and

(3) Indicates when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.104 Election to claim payment for emergency services furnished during a calendar year.

(a) *Terms of the election.* The hospital agrees to the following:

(1) To comply with the provisions of subpart C of part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(2) To comply with the provisions of subpart D of part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of a beneficiary.

(3) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(b) *Filing of election statement.* An election statement must be filed on a form designated by CMS, signed by an authorized official of the hospital, and either received by CMS, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If CMS accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which CMS determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to qualify.* If CMS has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, CMS will not accept another election statement from that hospital until CMS finds that—

(1) The reason for its failure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

§ 424.106 Criteria for determining whether the hospital was the most accessible.

(a) *Basic requirement.* (1) The hospital must be the most accessible one available and equipped to furnish the services.

(2) CMS determines accessibility based on the factors specified in paragraphs (b) and (c) of this section and the conditions set forth in paragraph (d) of this section.

(b) *Factors that are considered.* CMS considers the following factors in determining whether a nonparticipating hospital in a rural area meets the accessibility requirements:

(1) The relative distances of participating and nonparticipating hospitals in the area.

(2) The transportation facilities available to these hospitals.

(3) The quality of the roads to each hospital.

(4) The availability of beds at each hospital.

(5) Any other factors that bear on whether or not the services could be provided sooner in the nonparticipating hospitals than in a participating hospital in the general area.

In urban and suburban areas where both participating and nonparticipating hospitals are similarly available, CMS presumes that the services could have been provided in a participating hospital unless clear and convincing evidence shows that there was a medical or practical need to use the nonparticipating hospital.

(c) *Factors that are not considered.* CMS gives no consideration to the following factors in determining whether the nonparticipating hospital was the most accessible hospital:

(1) The personal preference of the beneficiary, the physician, or members of the family.

(2) The fact that the attending physician did not have staff privileges in a participating hospital which was available and the most accessible to the beneficiary.

(3) The location of previous medical records.

(d) *Conditions under which the accessibility requirement is met.* If a beneficiary must be taken to a hospital immediately for required diagnosis and treatment, the nonparticipating hospital meets the accessibility requirement if—

(1) It was the nearest hospital to the point where the emergency occurred, it

was medically equipped to handle the type of emergency, and it was the most accessible, on the basis of the factors specified in paragraph (b) of this section; or

(2) There was a closer participating hospital equipped to handle the emergency, but the participating hospital did not have a bed available or would not accept the individual.

§ 424.108 Payment to a hospital.

(a) *Conditions for payment.* Medicare pays the hospital for emergency services if the hospital—

(1) Has in effect a statement of election to claim payment for all covered emergency services furnished during a calendar year, in accordance with § 424.104;

(2) Claims payment in accordance with § 424.32; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Subsequent claims.* If the hospital files subsequent claims because the initial claim did not include all the services furnished, those claims must include physicians' statements that—

(1) Contain sufficient information to clearly establish that, when the additional services were furnished, the emergency still existed; and

(2) Indicate when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.109 Payment to the beneficiary.

Medicare pays the beneficiary for emergency services if the following conditions are met:

(a) The hospital does not have in effect an election to claim payment.

(b) The beneficiary, or someone on his or her behalf, submits—

(1) A claim that meets the requirements of § 424.32;

(2) An itemized hospital bill; and

(3) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

§ 424.120 Scope.

This subpart sets forth the conditions for payment for services furnished in a foreign country.

§ 424.121 Scope of payments.

Subject to the conditions set forth in this subpart—

(a) Medicare Part A pays, in the amounts specified in § 413.74 of this chapter, for emergency and nonemergency inpatient hospital services furnished by a foreign hospital.

(b) Medicare Part B pays for certain physicians' services and ambulance services furnished in connection with covered inpatient care in a foreign hospital, as specified in § 424.124.

(c) All other services furnished outside the United States are excluded from Medicare coverage, as specified in § 411.9 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.122 Conditions for payment for emergency inpatient hospital services.

Medicare Part A pays for emergency inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) At the time of the emergency that required the inpatient hospital services, the beneficiary was—

(1) In the United States; or

(2) In Canada traveling between Alaska and another State without unreasonable delay and by the most direct route.

(b) The foreign hospital was closer to, or more accessible from, the site of the emergency than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The conditions for payment for emergency services set forth in § 424.103 are met.

(d) The hospital is a hospital as defined in § 424.101, and is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located.

(e) The determination of whether the hospital was more accessible is made in accordance with § 424.106.

§ 424.123 Conditions for payment for nonemergency inpatient services furnished by a hospital closer to the individual's residence.

Medicare Part A pays for inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) The beneficiary is a resident of the United States.

(b) The foreign hospital is closer or more accessible to the beneficiary's residence than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The foreign hospital is—

(1) A hospital as defined in § 424.101 and, it is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located; and

(2) Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or accredited or approved by a program of the country where it is located under standards the CMS finds to be essentially equivalent to those of the JCAHO.

(d) The services are covered services that Medicare would pay for if they were furnished by a participating hospital.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.124 Conditions for payment for physician services and ambulance services.

(a) *Basic rules.* Medicare Part B pays for physician and ambulance services if—

(1) They are furnished—

(i) To an individual who is entitled to Part B benefits; and

(ii) In connection with covered inpatient hospital services; and

(2) They meet the conditions set forth in paragraphs (b) and (c) of this section.

(b) *Physician services.* (1) The physician services are services covered under Medicare Part B and are furnished—

(i) In the hospital, during a period of covered inpatient services; or

(ii) Outside the hospital, on the day of admission and for the same condition that required inpatient admission; and

(2) The physician is legally authorized to practice in the country where he or she furnishes the services.

(c) *Ambulance services.* The ambulance services are—

(1) Necessary because the use of other means of transportation is contraindicated by the beneficiary's condition; and

(2) Furnished by an ambulance that meets the definition in § 410.41 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 64 FR 3649, Jan. 25, 1999]

§ 424.126 Payment to the hospital.

(a) *Conditions for payment.* Medicare pays the hospital if it—

(1) Has in effect an election that—

(i) Meets the requirements set forth in § 424.104; and

(ii) Reflects the hospital's intent to claim for all covered services furnished during a calendar year.

(2) Claims payment in accordance with §§ 424.32 and 413.74 of this chapter; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount of payment.* Payment is made (in accordance with § 413.74 of this chapter) on the basis of 100 percent of the hospital's customary charges, subject to the applicable deductible and coinsurance provisions set forth elsewhere in this chapter.

§ 424.127 Payment to the beneficiary.

(a) *Conditions for payment of inpatient hospital services.* Medicare pays the beneficiary if—

(1) The hospital does not have in effect an election to claim payment; and

(2) The beneficiary, or someone on his or her behalf, submits—

(i) A claim in accordance with § 424.32;

(ii) An itemized hospital bill; and

(iii) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount payable for inpatient hospital services.* The amount payable to the beneficiary is determined in accordance with § 424.109(b).

(c) *Conditions for payment for Part B services.* Medicare pays the beneficiary for physicians' services and ambulance services as specified in § 424.121, if an itemized bill for the services is submitted by the beneficiary or someone on his or her behalf and the conditions of § 424.126(a) (2) and (3) are met.

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subparts I–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *U.S. Government checks*—(1) *Responsibility.* The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of CMS.

(2) *Action by CMS.* CMS forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuing checks.

(3) *Action by the Treasury Department.* The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR parts 235, 240, and 245).

(b) *Intermediary and carrier benefit checks.* Checks issued by intermediaries and carriers are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Replacement procedures are carried out in accordance with § 424.352 under applicable State law (including any Federal banking laws or regulations that may affect the relevant State proceedings).

[58 FR 65129, Dec. 13, 1993]

§ 424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed or paid on forged endorsements.

(a) When an intermediary or carrier is notified by a payee that a check has been lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsement, the intermediary or carrier contacts the commercial bank on whose paper the check was drawn and determines whether the check has been negotiated.

(b) If the check has been negotiated—

(1) The intermediary or carrier provides the payee with a copy of the check and other pertinent information (such as a claim form, affidavit or questionnaire to be completed by the payee) required to pursue his or her claim in accordance with State law and commercial banking regulations.

(2) To pursue the claim, the payee must examine the check and certify (by completing the claim form, questionnaire or affidavit) that the endorsement is not the payee's.

(3) The claim form and other pertinent information is sent to the intermediary or carrier for review and processing of the claim.

(4) The intermediary or carrier reviews the payee's claim. If the intermediary or carrier determines that the claim appears to be valid, it forwards the claim and a copy of the check to the issuing bank. The intermediary or carrier takes further action to recover the proceeds of the check in accordance with the State law and regulations.

(5) Once the intermediary or carrier recovers the proceeds of the initial check, the intermediary or carrier issues a replacement check to the payee.

(6) If the bank of first deposit refuses to settle on the check for good cause, the payee must pursue the claim on his or her own and the intermediary or carrier will not reissue the check to the payee.

(c) If the check has not been negotiated—

(1) The intermediary or carrier arranges with the bank to stop payment on the check; and

(2) Except as provided in paragraph (d), the intermediary or carrier reissues the check to the payee.

(d) No check may be reissued under (c)(2) unless the claim for a replacement check is received by the intermediary or carrier no later than 1 year from the date of issuance of the original check, unless State law (including any applicable Federal banking laws or regulations that may affect the relevant State proceeding) provides a longer period which will control.

[58 FR 65130, Dec. 13, 1993]

Subparts N–O [Reserved]

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

SOURCE: 71 FR 20776, Apr. 21, 2006, unless otherwise noted.

§ 424.500 Scope.

The provisions of this subpart contain the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.

§ 424.502 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and be granted Medicare billing privileges.

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

Deactivate means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

Delegated official means an individual who is delegated by the ''Authorized Official,'' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered services and supplies. The process includes—

(1) Identification of a provider or supplier;

(2) Validation of the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries;

(3) Identification and confirmation of the provider or supplier's practice location(s) and owner(s); and

(4) Granting the provider or supplier Medicare billing privileges.

Enrollment application means a CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by OMB.

Final adverse action means one or more of the following actions:

(1) A Medicare-imposed revocation of any Medicare billing privileges;

(2) Suspension or revocation of a license to provide health care by any State licensing authority;

(3) Revocation or suspension by an accreditation organization;

(4) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a Federal or State health care program.

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier.

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

Physician or nonphysician practitioner organization means any physician or nonphysician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information, or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier's billing privileges are terminated.

Voluntary termination means that a provider or supplier, including an individual physician or nonphysician practitioner, submits written confirmation to CMS of its decision to discontinue enrollment in the Medicare program.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69939, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 76 FR 5962, Feb. 2, 2011]

§ 424.505 Basic enrollment requirement.

To receive payment for covered Medicare items or services from either Medicare (in the case of an assigned claim) or a Medicare beneficiary (in the case of an unassigned claim), a provider or supplier must be enrolled in the Medicare program. Once enrolled, the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was furnished or a service that was rendered. (See 45 CFR part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

(a) *Definition. Eligible professional* means any of the professionals specified in section 1848(k)(3)(B) of the Act.

(b) *Enrollment requirements.* (1) A provider or a supplier that is eligible for an NPI must do the following:

(i) Report its NPI on its Medicare enrollment application.

(ii) If the provider or supplier was in the Medicare program before obtaining an NPI and the provider's or the supplier's NPI is not in the provider's or supplier's Medicare enrollment record, the provider or supplier must update its Medicare enrollment record by submitting its NPI using either of the following:

(A) The applicable paper CMS–855 form.

(B) Internet-based PECOS.

(2) A physician or eligible professional who has validly opted-out of the Medicare program is not required to submit a Medicare enrollment application for any reason, including to order or certify.

(c) *Claims reporting requirements.* (1) A provider or supplier that is enrolled in Medicare and submits a paper or an electronic claim must include its NPI and the NPI(s) of any other provider(s) or supplier(s) identified on the claim.

(2) A Medicare beneficiary who submits a claim for service to Medicare—

(i) Must include the legal name of any provider or supplier who is required to be identified in that claim; and

(ii) May, if known to the beneficiary, include the National Provider Identifier (NPI) of any provider or supplier who is required to be identified in that claim.

(3) A Medicare contractor will reject a claim from a provider or a supplier if the required NPI(s) is not reported.

[75 FR 24448, May 5, 2010, as amended at 77 FR 25317, Apr. 27, 2012]

§ 424.507 Ordering covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered covered imaging and clinical laboratory services and items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)*—(1) *Ordered covered imaging, clinical laboratory services, and DMEPOS item claims.* To receive payment for ordered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in § 424.507(b), and Part B drugs), a provider or supplier must meet all of the following requirements:

(i) The ordered covered imaging, clinical laboratory services, and DMEPOS items (excluding home health services described in paragraph (b) of this section, and Part B drugs) must have been ordered by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered the item or service.

(iii) The physician or, when permitted, other eligible professional, as defined in § 424.506(a), who ordered the item or service must—

(A) Be identified by his or her legal name;

(B) Be identified by his or her NPI; and

(C)(*1*) Be enrolled in Medicare in an approved status; or

(*2*) Have validly opted-out of the Medicare program.

(iv) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75), or by a non-enrolled licensed resident (as defined in § 413.75), the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status, as follows:

(*1*) As the ordering supplier.

(*2*) By his or her legal name.

(*3*) By his/her NPI.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or be otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or order such items and services, the claim must identify by legal name and NPI the—

(*1*) Resident, who is enrolled in Medicare in an approved status to order; or

(*2*) Teaching physician, who is enrolled in Medicare in an approved status.

(2) *Part B beneficiary claims.* To receive payment for ordered covered items and services listed at § 424.507(a), a beneficiary's claim must meet all of the following requirements:

(i) The physician or, when permitted, other eligible professional (as defined § 424.506(a)) who ordered the item or service must—

(A) Be identified by his or her legal name; and

(B)(*1*) Be enrolled in Medicare in an approved status; or

(*2*) Have validly opted out of the Medicare program.

(ii) If the item or service is ordered by—

(A) An unlicensed resident (as defined in § 413.75) or a non-enrolled licensed resident, (as defined in § 413.75) the claim must identify a teaching physician, who must be enrolled in Medicare in an approved status as follows:

(*1*) As the ordering supplier.

(*2*) By his or her legal name.

(B) A licensed resident (as defined in § 413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order such items and services, the claim must identify by legal name the—

(*1*) Resident, who is enrolled in Medicare in an approved status to order; or

(*2*) Teaching physician, who is enrolled in Medicare in an approved status.

(b) *Conditions for payment of claims for covered home health services.* To receive payment for covered Part A or Part B home health services, a provider's home health services claim must meet all of the following requirements:

(1) The ordering/certifying physician must meet all of the following requirements:

(i) Be identified by his or her legal name.

(ii) Be identified by his or her NPI.

(iii)(A) Be enrolled in Medicare in an approved status; or

(B) Have validly opted-out of the Medicare program.

(2) If the services were ordered/certified by—

(i) An unlicensed resident, as defined in § 413.75, or by a non-enrolled licensed resident, as defined in § 413.75, the claim must identify a teaching physician who must be enrolled in Medicare in an approved status—

(A) As the ordering/certifying supplier;

(B) By his or her legal name; and

(C) By his or her NPI.

(ii) A licensed resident (as defined in § 413.75), he or she must have a provisional license or are otherwise permitted by State law, where the resident is enrolled in an approved graduate medical education program, to practice or to order/certify such items and services, the claim must identify by legal name and NPI the—

(A) Resident, who is enrolled in Medicare in an approved status to order; or

(B) Teaching physician, who is enrolled in Medicare in an approved status.

(c) *Denial of provider- or supplier-submitted claims.* Notwithstanding § 424.506(c)(3), a Medicare contractor denies a claim from a provider or a supplier for covered items and services described in paragraph (a) or (b) of this section if the claim does not meet the requirements of paragraphs (a)(1) and (b) of this section, respectively.

(d) *Denial of beneficiary-submitted claims.* A Medicare contractor denies a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(2) of this section.

[77 FR 25317, Apr. 27, 2012]

§ 424.510 Requirements for enrolling in the Medicare program.

(a) Providers and suppliers must submit enrollment information on the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process, including, if applicable, a State survey and certification or accreditation process, CMS enrolls the provider or supplier into the Medicare program. To be enrolled, a provider or supplier must meet enrollment requirements specified in paragraph (d) of this section.

(b) The effective dates for reimbursement are specified in § 489.13 of this chapter for providers and suppliers requiring State survey or certification or accreditation, § 424.5 and § 424.44 for non-surveyed or certified/accredited suppliers, and § 424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers.

(c) The effective date for reimbursement for providers and suppliers seeking accreditation from a CMS-approved

accreditation organization as specified in § 489.13.

(d) Providers and suppliers must meet the following enrollment requirements:

(1) *Submittal of the enrollment application.* A provider or supplier must submit a complete enrollment application and supporting documentation to the designated Medicare fee-for-service contractor.

(2) *Content of the enrollment application.* Each submitted enrollment application must include the following:

(i) Complete, accurate, and truthful responses to all information requested within each section as applicable to the provider or supplier type.

(ii) Submission of all documentation required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to uniquely identify the provider or supplier. This documentation may include, but is not limited to, proof of the legal business name, practice location, social security number (SSN), tax identification number (TIN), National Provider Identifier (NPI), if issued, and owners of the business.

(iii) Submission of all documentation, including—

(A) All applicable Federal and State licenses, certifications including, but not limited to Federal Aviation Administration; and

(B) Documentation associated with regulatory and statutory requirements necessary to establish a provider's or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program.

(iv) At the time of enrollment, an enrollment change request, revalidation or change of Medicare contractors where the provider or supplier was already receiving payments via EFT, providers and suppliers must agree to receive Medicare payments via EFT, if not already receiving payment through EFT. In order to receive Medicare payments via EFT, providers and suppliers must submit the CMS–588 form.

(3) *Signature(s) required on the enrollment application.* The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in this chapter. This person must also have an ownership or control interest in the provider or supplier, as that term is defined in section 1124(a)(3) of the Act, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.

(i) *Requirements.* The signature requirements specified in paragraphs (d)(3)(i)(A) through (C) of this section outline who must sign the enrollment application for an enrolling provider or supplier. In the case of—

(A) An individual practitioner, the applying practitioner.

(B) A sole proprietorship, the applying sole proprietor.

(C) A corporation, partnership, group, limited liability company, or other organization (hereafter referred to collectively in this section as an organization), an authorized official, as defined in § 424.502. When an authorized official signs the certification statement on behalf of an organization, the signed statement is considered legally binding upon the organization.

(ii) *Delegation of authority.* The original enrollment application submitted for an organization's initial enrollment and all subsequent enrollment applications submitted for periodic revalidation of the organization's enrollment data (as required to maintain enrollment in the Medicare program) must be signed by an authorized official. Any updates or changes reported outside of the initial enrollment or periodic revalidation process may be signed by a delegated official(s) of the organization. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of the authorized official currently on file with Medicare.

Once the delegation of authority is established, the only acceptable signatures on correspondence to report updates or changes to the enrollment information are those of the authorized official and the person(s) to whom this authority is delegated in accordance with the requirements described in this section. Individual practitioners and sole proprietors cannot delegate signature authority when submitting an enrollment application for any reason. All enrollment applications submitted by individual practitioners and sole proprietors must be signed by the enrolling or enrolled individual. Each delegation of authority to a delegated official must—

(A) Be assigned by the authorized official currently on file with CMS;

(B) Be submitted to CMS using the appropriate enrollment application or CMS established electronic enrollment process;

(C) Include the title and SSN of each person delegated authority to update or change the organization's enrollment information;

(D) Be an individual that has an ownership or control interest in the organization or is a W–2 managing employee as defined in section 1126(b) of the Act; and

(E) Be signed by the authorized official and the delegated official(s) of the organization.

(4) *Verification of information.* The information submitted by the provider or supplier on the applicable enrollment application must be such that CMS can validate it for accuracy at the time of submission.

(5) *Completion of any applicable State surveys, certifications, and provider agreements.* The providers or suppliers who are mandated under the provision in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to also enter into and sign a provider agreement as outlined in part 489 of this chapter, must also meet those requirements as part of the process to obtain Medicare billing privileges.

(6) *Ability to furnish Medicare covered items or services.* The provider or supplier must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges.

(7) *Additional requirements.* Providers and suppliers must meet the provisions of §424.520 regarding additional compliance and reporting requirements.

(8) *On-site review.* CMS reserves the right, when deemed necessary, to perform on-site inspections of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(i) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(9) In order to obtain enrollment and to maintain enrollment for the first three months after Medicare billing privileges are conveyed, a home health agency must satisfy the home health ''initial reserve operating funds'' requirement as set forth in §489.28 of this chapter.

(e) Providers and suppliers must—

(1) Agree to receive Medicare payment via electronic funds transfer (EFT) at the time of enrollment, revalidation, change of Medicare contractors where the provider or supplier was already receiving payments via EFT or submission of an enrollment change request; and

(2) Submit the CMS–588 form to receive Medicare payment via electronic funds transfer.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 75 FR 50418, Aug. 16, 2010; 75 FR 70464, Nov. 17, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 29030, July 16, 2012]

§ 424.514 Application fee.

(a) *Application fee requirements for prospective institutional providers.* Beginning on or after March 25, 2011, prospective institutional providers that are submitting an initial application or currently enrolled institutional providers that are submitting an application to establish a new practice location must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) *Application fee requirements for revalidating institutional providers.* Beginning March 25, 2011, institutional providers that are subject to CMS revalidation efforts must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) *Hardship exception for disaster areas.* CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) should receive an exception to the application fee.

(d) *Application fee.* The application fee and associated requirements are as follows:

(1) For 2010, $500.00.

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a CMS revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable, except if submitted with one of the following:

(A) A request for hardship exception that is subsequently approved;

(B) An application that is rejected prior to initiation of screening processes;

(C) An application that is subsequently denied as a result of the imposition of a temporary moratorium;

(e) *Denial or revocation based on application fee.* A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application, the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor may—

(1) Reject an enrollment application from a newly-enrolling institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(3)(i) Notwithstanding the foregoing, the contractor must first inform the provider that the application fee was not submitted in accordance with this section.

(ii) Within 30 days after the date of the notification, the contractor may reject the application of the newly-enrolling institutional provider or revoke the billing privileges of the currently enrolled institutional provider that has not submitted the fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to

approve or disapprove a hardship exception request. If a provider submits a request for hardship exception to the fee and the provider or supplier has not already submitted the fee consistent with provisions in §424.514(a) and (b), and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception request was not approved and allows the provider or supplier 30 days from the date of notification to submit the application fee.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using §405.874 of this chapter.

[76 FR 5962, Feb. 2, 2011]

§424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.

To maintain Medicare billing privileges, a provider or supplier (other than a DMEPOS supplier) must resubmit and recertify the accuracy of its enrollment information every 5 years. All providers and suppliers currently billing the Medicare program or initially enrolling in the Medicare program are required to complete the applicable enrollment application. The provider or supplier then enters a 5-year revalidation cycle once a completed enrollment application is submitted and validated. (Ambulance service providers must continue to resubmit enrollment information in accordance with §410.41(c)(2) of this chapter and DMEPOS suppliers must continue to renew enrollment in accordance with §424.57(e)). The requirements for the resubmission, recertification and reverification of enrollment information include the following:

(a) *Submission of the enrollment application and supporting documentation.* The provider or supplier must meet the submission, content, signature, verification, operational, inspection, and other requirements outlined in §424.510.

(1) CMS contacts each provider or supplier directly when it is time to revalidate their enrollment information.

(2) A provider or supplier must submit to CMS the applicable enrollment application with complete and accurate information and applicable supporting documentation within 60 calendar days of our notification to resubmit and certify to the accuracy of its enrollment information.

(b) *Completion of any applicable State surveys, certifications and provider agreements.* A new certification and a new provider agreement are not required for the purpose of resubmission and certification for revalidation of enrollment information. Providers and suppliers must continue to meet the requirements of parts 488 and 489 of this chapter, or any currently established supplier agreement, if applicable.

(c) *On-site inspections.* CMS reserves the right to perform on-site inspections of a provider or supplier to verify that the information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(d) *Off Cycle revalidations.* (1) CMS reserves the right to perform off cycle revalidations in addition to the regular 5-year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by CMS. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits.

(2) CMS reserve the right to adjust the routine 5-year revalidation schedule if we determine that revalidation should occur on a more frequent basis due to complaints or evidence we receive indicating noncompliance with the statute or regulations by specific provider or supplier types. The schedule may also be on a less frequent basis if we determine that the integrity of and compliance with the statute and regulations by specific provider or supplier types indicates that less frequent validation is justified. If a change occurs, CMS notifies all affected providers and suppliers at least 90 days in advance of implementing the change.

(3) CMS revalidates enrollment information for ambulance service suppliers in accordance with §410.41(c)(2) of this chapter (Requirements for ambulance suppliers), and DMEPOS suppliers renews enrollment in accordance with §424.57(e) (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at §424.518.

[71 FR 20776, Apr. 21, 2006, as amended at 76 FR 5963, Feb. 2, 2011]

§424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

(a) *Certifying compliance.* CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:

(1) Compliance with title XVIII of the Act and applicable Medicare regulations.

(2) Compliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

(3) Not employing or contracting with individuals or entities that meet either of the following conditions:

(i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A(a)(6) of the Act.

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.

(b) *Reporting requirements Independent Diagnostic Testing Facilities (IDTFs).* IDTF reporting requirements are specified in §410.33(g)(2) of this chapter.

(c) *Reporting requirements DMEPOS suppliers.* DMEPOS reporting requirements are specified in §424.57(c)(2).

(d) *Reporting requirements for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* Physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations must report the following reportable events to their Medicare contractor within the specified timeframes:

(1) Within 30 days—
(i) A change of ownership;
(ii) Any adverse legal action; or
(iii) A change in practice location.
(2) All other changes in enrollment must be reported within 90 days.

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, must report to CMS the following information within the specified timeframes:

(1) Within 30 days for a change of ownership or control, including changes in authorized official(s) or delegated official(s);

(2) All other changes to enrollment must be reported within 90 days.

(3) Within 30 days of any revocation or suspension of a Federal or State license or certification including Federal Aviation Administration certifications, an air ambulance supplier must report a revocation or suspension of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

(i) Specific pilot certifications including but not limited to instrument and medical certifications.

(ii) Airworthiness certification.

(f) *Maintaining and providing access to documentation.* (1)(i) A provider or a supplier that furnishes covered ordered items of DMEPOS, clinical laboratory, imaging services, or covered ordered/certified home health services is required to—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

(2)(i) A physician who orders/certifies home health services and the physician or, when permitted, other eligible professional who orders items of DMEPOS or clinical laboratory or imaging services is required to—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered the items of DMEPOS or the clinical laboratory or imaging services) relating to written orders or certifications or requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

[73 FR 69939, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008, as amended at 75 FR 24449, May 5, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 25318, Apr. 27, 2012]

§424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges as specified in §424.530 or §424.535 of this part.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider meets either of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B providers.* CMS determines, upon review, that the supplier meets any of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any or all of the Medicare enrollment requirements.

(iii) Has failed to furnish Medicare covered items or services as required by the statute or regulations.

(b) [Reserved]

[73 FR 66940, Nov. 19, 2008]

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, including applications for a new practice location, and any applications received in response to a revalidation request based on a CMS assessment of risk and assignment to a level of ''limited,'' ''moderate,'' or ''high.''

(a) *Limited categorical risk*—(1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as ''limited'' categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(viii) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(ix) Mammography screening centers.

(x) Mass immunization roster billers

(xi) Organ procurement organizations.

(xii) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xiii) Radiation therapy centers.

(xiv) Religious non-medical health care institutions.

(xv) Rural health clinics.

(xvi) Skilled nursing facilities.

(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a ''limited'' categorical level of risk, the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk*—(1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as ''moderate'' categorical risk:

(i) Ambulance service suppliers.

(ii) Community mental health centers.

(iii) Comprehensive outpatient rehabilitation facilities.

(iv) Hospice organizations.

(v) Independent clinical laboratories.

(vi) Independent diagnostic testing facilities.

(vii) Physical therapists enrolling as individuals or as group practices.

(viii) Portable x-ray suppliers.

(ix) Revalidating home health agencies.

(x) Revalidating DMEPOS suppliers.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a ''moderate'' categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the ''limited'' screening requirements described in paragraph (a)(2) of this section.

(ii) Conducts an on-site visit.

(c) *High categorical risk*—(1) *High categorical risk: Provider and supplier categories.* CMS has designated the following home health agencies and suppliers of DMEPOS as ''high'' categorical risk:

(i) Prospective (newly enrolling) home health agencies.

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a ''high'' categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the ''limited'' and ''moderate'' screening requirements described in paragraphs (a)(2) and (b)(2) of this section.

(ii)(A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

(B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from ''limited'' or ''moderate'' to ''high'' if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.

(ii) The provider or supplier—

(A) Has been excluded from Medicare by the OIG; or

(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—

(*1*) Enrolling as a new provider or supplier; or

(*2*) Billing privileges for a new practice location;

(C) Has been terminated or is otherwise precluded from billing Medicaid;

(D) Has been excluded from any Federal health care program; or

(E) Has been subject to any final adverse action, as defined at § 424.502, within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints for a national background check.

(i) Upon submission of a Medicare enrollment application; or

(ii) Within 30 days of a Medicare contractor request.

(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section, the provider or supplier will have its billing privileges—

(i) Denied under § 424.530(a)(1); or

(ii) Revoked under § 424.535(a)(1).

[76 FR 5963, Feb. 2, 2011]

§ 424.520 Effective date of Medicare billing privileges.

(a) *Surveyed, certified or accredited providers and suppliers.* The effective date for billing privileges for providers and suppliers requiring State survey, certification or accreditation is specified in § 489.13 of this chapter. If a provider or supplier is seeking accreditation from a CMS-approved accreditation organization, the effective date is specified in § 489.13.

(b) *Independent Diagnostic Testing Facilities.* The effective date for billing privileges for IDTFs is specified in § 410.33(i) of this chapter.

(c) *DMEPOS suppliers.* The effective date for billing privileges for DMEPOS suppliers is specified in § 424.57(b) of this subpart and section 1834(j)(1)(A) of the Act.

(d) *Physicians, nonphysician practitioners, and physician and nonphysician*

practitioner organizations. The effective date for billing privileges for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations is the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor or the date an enrolled physician or nonphysician practitioner first began furnishing services at a new practice location.

[73 FR 69940, Nov. 19, 2008, as amended at 75 FR 50418, Aug. 16, 2010]

§ 424.521 Request for payment by physicians, nonphysician practitioners, physician or nonphysician organizations.

(a) Physicians, nonphysician practitioners and physician and nonphysician practitioner organizations may retrospectively bill for services when a physician or nonphysician practitioner or a physician or a nonphysician organization have met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

(1) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

(2) 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(b) [Reserved]

[73 FR 69940, Nov. 19, 2008]

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

(1) The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the contractor request for the missing information.

(2) The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

(3) The prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend the 30 day period if CMS determines that the prospective provider or supplier is actively working with CMS to resolve any outstanding issues.

(c) *Resubmission after rejection.* To enroll in Medicare and obtain Medicare billing privileges after notification of a rejected enrollment application, the provider or supplier must complete and submit a new enrollment application and submit all supporting documentation for CMS review and approval.

(d) *Additional review.* Enrollment applications that are rejected are not afforded appeal rights.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008; 76 FR 5964, Feb. 2, 2011]

§ 424.530 Denial of enrollment in the Medicare program.

(a) *Reasons for denial.* CMS may deny a provider's or supplier's enrollment in the Medicare program for the following reasons:

(1) *Compliance.* The provider or supplier at any time is found not to be in compliance with the Medicare enrollment requirements described in this section or on the applicable enrollment application to the type of provider or supplier enrolling, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) *Provider or supplier conduct.* A provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application, in accordance with section 1862(e)(1) of the Act, is—

(i) Excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in § 1001.2 of this chapter, in accordance with section

1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(3) *Felonies.* If within the 10 years preceding enrollment or revalidation of enrollment, the provider, supplier, or any owner of the provider or supplier, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. CMS considers the severity of the underlying offense.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, or assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct).

(D) Any felonies outlined in section 1128 of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) *False or misleading information.* The provider or supplier has submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.)

(5) *On-site review.* Upon on-site review or other reliable evidence, we determine that the provider or supplier is not operational, or is not meeting Medicare enrollment requirements to furnish Medicare covered items or services. Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(6) *Overpayment.* The current owner (as defined in §424.502), physician or nonphysician practitioner has an existing overpayment at the time of filing of an enrollment application.

(7) *Payment suspension.* The current owner (as defined in §424.502), physician or nonphysician practitioner has been placed under a Medicare payment suspension as defined in §405.370 through §405.372 of this subchapter.

(8) *Initial Reserve Operating Funds.* (i) CMS or its designated Medicare contractor may deny Medicare billing privileges if, within 30 days of a CMS or Medicare contractor request, a home health agency (HHA) cannot furnish supporting documentation which verifies that the HHA meets the initial reserve operating funds requirement found in §489.28(a) of this title.

(ii) CMS may deny Medicare billing privileges upon an HHA applicant's failure to satisfy the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(9) *Application fee/hardship exception.* An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.

(10) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

(b) *Resubmission after denial.* A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application

until the following has occurred if the denial:

(1) Was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) Was appealed, the provider or supplier may reapply after notification that the determination was upheld.

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

(d) *Additional review.* When a provider or supplier is denied enrollment in Medicare, CMS automatically reviews all other related Medicare enrollment files that the denied provider or supplier has an association with (for example, as an owner or managing employee) to determine if the denial warrants an adverse action of the associated Medicare provider or supplier.

(e) *Effective date of denial.* Denial becomes effective within 30 days of the initial denial notification.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 69940, Nov. 19, 2008; 75 FR 70464, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011]

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:

(1) *Noncompliance.* The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter. All providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges, except for those imposed under paragraphs (a)(2), (a)(3), or (a)(5) of this section.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is—

(i) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(3) *Felonies.* The provider, supplier, or any owner of the provider or supplier, within the 10 years preceding enrollment or revalidation of enrollment, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was

convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) *False or misleading information.* The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

(5) *On-site review.* CMS determines, upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients. Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) Either of the following occurs:

(*1*) CMS is not able to deposit the full application amount into a government-owned account.

(*2*) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

(7) *Misuse of billing number.* The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in § 424.80 or a change of ownership as outlined in § 489.18 of this chapter.

(8) *Abuse of billing privileges.* The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

(9) *Failure to report.* The provider or supplier did not comply with the reporting requirements specified in § 424.516(d)(1)(ii) and (iii) of this subpart.

(10) *Failure to document or provide CMS access to documentation.* (i) The provider or supplier did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

(11) *Initial reserve operating funds.* CMS or its designated Medicare contractor may revoke the Medicare billing privileges of an HHA and the corresponding provider agreement if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR 489.28(a).

(12) *Medicaid termination.* (i) Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(ii) Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.

(b) *Effect of revocation on provider agreements.* When a provider's or supplier's billing privilege is revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

(c) *Reapplying after revocation.* After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation. The re-enrollment bar does not apply in the event a revocation of Medicare billing privileges is imposed under paragraph (a)(1) of this section based upon a provider or supplier's failure to respond timely to a revalidation request or other request for information.

(d) *Re-enrollment after revocation.* If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing privileges is revoked (either after the appeals process is exhausted or in place of the appeals process), the following conditions apply:

(1) The provider or supplier must reenroll in the Medicare program through the completion and submission of a new applicable enrollment application and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be resurveyed and recertified by the State survey agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, or an authorized or delegated official; or a medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

(f) *Additional review.* When a provider or supplier is revoked from the Medicare program, CMS automatically reviews all other related Medicare enrollment files that the revoked provider or supplier has an association with (for example, as an owner or managing employee) to determine if the revocation warrants an adverse action of the associated Medicare provider or supplier.

(g) *Effective date of revocation.* Revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(h) *Submission of claims for services furnished before revocation.* A physician organization, physician, nonphysician practitioner or independent diagnostic testing facility must submit all claims for items and services furnished within

60 calendar days of the effective date of revocation.

[71 FR 20776, Apr. 21, 2006, as amended at 72 FR 53648, Sept. 19, 2007; 73 FR 36461, June 27, 2008; 73 FR 69940, Nov. 19, 2008; 75 FR 24449, May 5, 2010; 75 FR 70465, Nov. 17, 2010; 76 FR 5964, Feb. 2, 2011; 77 FR 25318, Apr. 27, 2012; 77 FR 29030, May 16, 2012]

§ 424.540 Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation.* CMS may deactivate the Medicare billing privileges of a provider or supplier for any of the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in §§ 424.520(b) and 424.550(b).

(3) The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(b) *Reactivation of billing privileges.* (1) When deactivated for any reason other than nonsubmission of a claim, the provider or supplier must complete and submit a new enrollment application to reactivate its Medicare billing privileges or, when deemed appropriate, at a minimum, recertify that the enrollment information currently on file with Medicare is correct.

(2) Providers and suppliers deactivated for nonsubmission of a claim are required to recertify that the enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim.

(3) Except as provided in paragraph (b)(3)(i) of this section, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at paragraph (a) of this section must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

(c) *Effect of deactivation.* Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any conditions of participation.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 77 FR 29030, May 16, 2012]

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A prospective provider or supplier that is denied enrollment in the Medicare program, or a provider or supplier whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 498, subpart A of this chapter.

(1) *Appeals resulting in the termination of a provider agreement.* (i) When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement.

(ii) When a provider appeals the revocation of billing privileges and the termination of its provider agreement, there will be one appeals process which

will address both matters. The appeal procedures for revocation of Medicare billing privileges will apply.

(2) *Payment of unpaid claims.* Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

(b) A provider or supplier whose billing privileges are deactivated may file a rebuttal in accordance with § 405.374 of this chapter.

(c) The provider or supplier must be able to demonstrate that it meets the enrollment requirements and it must be able to make available any documents and records that support the provisions of this regulation and the Medicare enrollment application if requested by CMS or its agents.

[71 FR 20776, Apr. 21, 2006, as amended at 73 FR 36461, June 27, 2008]

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

(a) *General rule.* A provider or supplier is prohibited from selling its Medicare billing number or privileges to any individual or entity, or allowing another individual or entity to use its Medicare billing number.

(b) *Change of ownership.* In the case of a provider undergoing a change of ownership in accordance with part 489, subpart A of this chapter, the current owner and the prospective new owner must complete and submit enrollment applications before completion of the change of ownership. If the current owner fails to complete and submit an enrollment application to report the change, the current owner may be sanctioned or penalized, even after the date of ownership change, in accordance with §§ 424.520, 424.540, and 489.53 of this chapter. If the prospective new owner fails to submit a new enrollment application containing information concerning the new owner within 30 days of the change of ownership, CMS may deactivate the Medicare billing number. If an incomplete enrollment application is submitted, CMS may also deactivate the Medicare billing number based upon material omissions on the submitted enrollment application, or based on preliminary information received or determined by CMS that makes CMS question whether the new owner is ultimately granted a final transference of the provider agreement.

(1) Unless an exception in (b)(2) of this section applies, if there is a change in majority ownership of a home health agency by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

(i) Enroll in the Medicare program as a new (initial) HHA under the provisions of § 424.510 of this subpart.

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2)(i) The HHA submitted two consecutive years of full cost reports. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.

(ii) An HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(iii) The owners of an existing HHA are changing the HHA's existing business structure (for example, from a corporation to a partnership (general or limited); from an LLC to a corporation; from a partnership (general or limited) to an LLC) and the owners remain the same.

(iv) An individual owner of an HHA dies.

(c) *Suppliers not covered by part 489 of this chapter.* For those suppliers not covered by part 489 of this chapter, any change in the ownership or control of that supplier must be reported on the enrollment application within 30 days of the change as noted in § 424.540(a)(2). Generally, a change of ownership that also changes the tax identification number requires the completion and submission of a new enrollment application from the new owner.

[71 FR 20776, Apr. 21, 2006, as amended at 74 FR 58134, Nov. 10, 2009; 75 FR 70465, Nov. 17, 2010; 75 FR 76293, Dec. 8, 2010]

§ 424.555 Payment liability.

(a) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by suppliers of durable medical equipment, prosthetics, orthotics, and other supplies unless the supplier obtains (and renews, as set forth in section 1834(j) of the Act) Medicare billing privileges.

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

(c) If any provider or supplier furnishes an otherwise Medicare covered item or service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier. The provider or supplier may also be criminally liable for pursuing payments that may not be made by reason of paragraph (b) of this section, in accordance with section 1128B(a)(3) of the Act.

§ 424.565 Overpayment.

A physician or nonphysician practitioner organization, physician or nonphysician practitioner that does not comply with the reporting requirements specified in § 424.516(d)(1)(ii) and (iii) of this subpart is assessed an overpayment back to the date of the final adverse action or change in practice location. Overpayments are processed in accordance with part 405 subpart C of this chapter.

[73 FR 69941, Nov. 19, 2008]

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) *Temporary moratoria*—(1) *General rules.* (i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area.

(ii) CMS will announce the temporary enrollment moratorium in a FEDERAL REGISTER document that includes the rationale for imposition of the temporary enrollment moratorium.

(iii) The temporary moratorium does not apply to changes in practice location, changes in provider or supplier information such as phone number, address or changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment under § 424.550).

(iv) The temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed.

(2) *Imposition of a temporary moratoria.* CMS may impose the temporary moratorium if—

(i) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a—

(A) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(B) Rapid increase in enrollment applications within a category;

(ii) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(iii) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(iv) CMS, in consultation the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(A) A particular provider or supplier type.

(B) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments. CMS will publish a document in the FEDERAL REGISTER when it extends a moratorium.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS will publish a document in the FEDERAL REGISTER when a moratorium is lifted. CMS may lift a temporary moratorium at any time after imposition of the moratorium if one of the following occur:

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act).

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability.

(3) The Secretary has declared a public health emergency under section 319 of the Public Health Service Act in the area subject to a temporary moratorium.

(4) In the judgment of the Secretary, the moratorium is no longer needed.

[76 FR 5965, Feb. 2, 2011]

PART 425—MEDICARE SHARED SAVINGS PROGRAM

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AUTHORITY: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 76 FR 67973, Nov. 2, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 425.10 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. The regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Application procedures and provisions of the participation agreement.

(3) Program requirements and beneficiary protections.

(4) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(5) Quality performance standards, reporting requirements, and data sharing.

(6) Payment criteria and methodologies (one-sided model and two-sided model).

(7) Compliance monitoring and sanctions for noncompliance.

(8) Reconsideration review process.

§ 425.20 Definitions.

As used in this part, unless otherwise indicated—

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants(s) that is(are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).

ACO participant means an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under § 425.204(c)(5).

ACO professional means an ACO provider/supplier who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he performs such function or action.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

ACO provider/supplier means an individual or entity that—

(1) Is a provider (as defined at § 400.202 of this chapter) or a supplier (as defined at § 400.202 of this chapter);

(2) Is enrolled in Medicare;

(3) Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and

(4) Is included on the list of ACO providers/suppliers that is required under § 425.204(c)(5).

Agreement period means the term of the participation agreement which begins at the start of the first performance year and concludes at the end of the final performance year.

Antitrust Agency means the Department of Justice or Federal Trade Commission.

Assignment means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from a physician who is an ACO provider/supplier so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.

At-risk beneficiary means, but is not limited to, a beneficiary who—

(1) Has a high risk score on the CMS–HCC risk adjustment model;

(2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern;

(5) Has one or more chronic conditions.

(6) Has had a recent diagnosis that is expected to result in increased cost.

(7) Is entitled to Medicaid because of disability; or

(8) Is diagnosed with a mental health or substance abuse disorder.

Continuously assigned beneficiary means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO's participant during the most recent prior calendar year.

Covered professional services has the same meaning given these terms under section 1848(k)(3)(A) of the Act.

Critical access hospital (CAH) has the same meaning given this term under § 400.202 of this chapter.

Eligible professional has the meanings given this term under section 1848(k)(3)(B) of the Act.

Federally qualified health center (FQHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under both parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

Newly assigned beneficiary means a beneficiary that is assigned in the current performance year who was neither assigned to nor receives a primary care service from any of the ACO's participants during the most recent prior calendar year.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under subpart G of this part.

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise noted in the ACO's agreement. For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months and 18 months, respectively.

Physician means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Physician Quality Reporting System (PQRS) means the quality reporting system established under section 1848(k) of the Act.

Primary care physician means a physician who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, or, for services furnished in an FQHC or RHC, a physician included in an attestation by the ACO as provided under § 425.404.

Primary care services mean the set of services identified by the following HCPCS codes:

(1) 99201 through 99215.

(2) 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit), G0438 and G0439 (codes for the annual wellness visits);

(3) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

Quality measures means the measures defined by the Secretary, under section 1899 of the Act, to assess the quality of care furnished by an ACO, such as measures of clinical processes and outcomes, patient and, where practicable, caregiver experience of care and utilization.

Reporting period, for purposes of subpart F of this part, means the calendar year from January 1 to December 31.

Rural health center (RHC) has the same meaning given to this term under § 405.2401(b).

Shared losses means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, above the applicable benchmark, it must repay to CMS. An ACO's eligibility for shared losses will be determined for each performance year. For an ACO requesting interim payment, shared losses may result from the interim payment calculation.

Shared savings means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, below the applicable benchmark, it is eligible to receive payment for from CMS. An ACO's eligibility for shared savings will be determined for each performance year. For an ACO requesting interim payment, shared savings may result from the interim payment system calculation.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G of this part.

Subpart B—Shared Savings Program Eligibility Requirements

§ 425.100 General.

(a) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that meets the criteria specified in this part. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) ACOs that meet or exceed a minimum savings rate established under § 425.604 or § 425.606, meet the minimum quality performance standards established under § 425.500, and otherwise

maintain their eligibility to participate in the Shared Savings Program under this part are eligible to receive payments for shared savings under subpart G.

(c) ACOs that operate under the two-sided model and meet or exceed a minimum loss rate established under § 425.606 must share losses with the Medicare program under subpart G of the part.

§ 425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) CAHs that bill under Method II (as described in § 413.70(b)(3) of this chapter).

(6) RHCs.

(7) FQHCs.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible participate through an ACO formed by one or more of the ACO participants identified in paragraph (a) of this section.

§ 425.104 Legal entity.

(a) An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for purposes of the following:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses or other monies determined to be owed to CMS.

(3) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in this part.

(b) An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

§ 425.106 Shared governance.

(a) *General rule.* An ACO must maintain an identifiable governing body with authority to execute the functions of an ACO as defined under this part, including but not limited to, the processes defined under § 425.112 to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.

(b) *Responsibilities of the governing body and its members.* (1) The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities as described in this part.

(2) The governing body must have a transparent governing process.

(3) The governing body members must have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.

(4) The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants.

(5) If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies the other requirements of this section.

(c) *Composition and control of the governing body.* (1) The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

(2) The ACO governing body must include a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(3) At least 75 percent control of the ACO's governing body must be held by ACO participants.

(4) The governing body members may serve in a similar or complementary manner for an ACO participant.

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraphs

(c)(2) and (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.

(d) *Conflict of interest.* The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—

(1) Require each member of the governing body to disclose relevant financial interests; and

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.

(3) The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.

§425.108 Leadership and management.

(a) An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) The ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

(c) Clinical management and oversight must be managed by a senior-level medical director who is a physician and one of its ACO providers/suppliers, who is physically present on a regular basis at any clinic, office, or other location participating in the ACO, and who is a board-certified physician and licensed in a State in which the ACO operates.

(d) Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.

(1) Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.

(2) A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by §425.112 and is held accountable for meeting the ACO's performance standards for each required process.

(e) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting paragraphs (b) through (c) of this section.

§425.110 Number of ACO professionals and beneficiaries.

(a)(1) The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subpart E of this part. The ACO must have at least 5,000 assigned beneficiaries.

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries specified in paragraph (a)(1) of this section if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period, using the assignment methodology in subpart E of this part, is 5,000 or more.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a CAP.

(1) While under the CAP, the ACO remains eligible for shared savings and losses during that performance year and its MSR will be set at a level consistent with the number of assigned beneficiaries.

(2) If the ACO's assigned population is not returned to at least 5,000 or more by the end of next performance year, the ACO's agreement will be terminated and the ACO will not be eligible

to share in savings for that performance year.

§ 425.112 Required processes and patient-centeredness criteria.

(a) *General.* (1) An ACO must—

(i) Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;

(ii) Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and

(iii) Have defined processes to fulfill these requirements.

(2) An ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes included in paragraphs (b)(1) through (4) of this section.

(3) For each process specified in paragraphs (b)(1) through (4) of this section, the ACO must—

(i) Explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and

(ii) Explain how it will employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

(b) *Required processes.* The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:

(1) Promote evidence-based medicine. These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.

(2) Promote patient engagement. These processes must address the following areas:

(i) Compliance with patient experience of care survey requirements in § 425.500.

(ii) Compliance with beneficiary representative requirements in § 425.106.

(iii) A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(A) In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.

(B) An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.

(iv) Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(v) Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;

(vi) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(3) Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.

(4) Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must—

(i) Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and

(ii) As part of its application, the ACO must:

(A) Submit a description of its individualized care program, along with a sample individual care plan, and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients.

(B) Describe additional target populations that would benefit from individualized care plans. Individual care plans must take into account the community resources available to the individual.

§ 425.114 Participation in other shared savings initiatives.

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

Subpart C—Application Procedures and Participation Agreement

§ 425.200 Agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than three years.

(b) *Term of agreement.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the agreement will be one of the following:

(i) April 1, 2012 (term of the agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the agreement is 3 years and 6 months).

(2) For 2013 and all subsequent years—

(i) The start date is January 1 of that year; and

(ii) The term of the agreement is 3 years.

(c) *Performance year.* (1) Except as specified in paragraphs (b)(1)(i) and (ii) of this section, the ACO's performance year under the agreement is the 12 month period beginning on January 1 of each year during the term of the agreement unless otherwise noted in its agreement.

(2) For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(d) During each calendar year of the agreement period, including the partial year associated with start dates specified in paragraph (b)(1)(i) and (ii) of this section, ACOs must submit measures in the form and manner required by CMS.

§ 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(c) *Application review.* (1) CMS determines whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program.

(2) CMS approves or denies applications accordingly.

§ 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Disclosure of prior participation.* (1) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare Shared Savings Program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO.

(2) The ACO must specify whether the related ACO agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must submit to CMS the following supporting materials to demonstrate that the ACO satisfies the eligibility requirements set forth in subpart B of this part:

(i) Documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, including how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidenced-based clinical guidelines.

(ii) A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under §425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.

(iii) Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders including administrative and clinical leaders specifically noted in §425.108.

(iv) Evidence that the governing body is an identifiable body, that the governing body is comprised of representatives of the ACO's participants, and that the ACO participants have at least 75 percent control of the ACO's governing body.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the ACO's agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(i) Charters.

(ii) By-laws.

(iii) Articles of incorporation.

(iv) Partnership agreement.

(v) Joint venture agreement.

(vi) Management or asset purchase agreements.

(vii) Financial statements and records.

(viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the—

(i) Governing body requirements in §425.106, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO

governance or provide meaningful representation in ACO governance by Medicare beneficiaries or both; or

(ii) Leadership and management requirements in § 425.108, the ACO must describe how its alternative leadership and management structure will be capable of accomplishing the ACO's mission.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among multiple, independent ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and their Medicare-enrolled TINs.

(A) For each ACO participant, the ACO must submit a list of the ACO providers/suppliers and their provider identifier (for example, NPI) and indicate whether the ACO provider/supplier is a primary care physician as defined in § 425.20.

(B) The list specified in paragraph (c)(5)(i)(A) of this section must be updated in accordance with § 425.302(d).

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) If the ACO includes an FQHC or RHC as an ACO participant, it must also do the following:

(A) Indicate the TINs, organizational NPIs, and other identifying information for its participant FQHCs or RHCs or both, as well as NPIs and other identifying information for the physicians that directly provide primary care services in the participant FQHCs or RHCs or both.

(B) Submit any other specific identifying information for its participant FQHCs or RHCs or both as required by CMS in the application process.

(iv) The ACO must certify the accuracy of this information.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe the following:

(1) How it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its ACO participants and ACO providers/suppliers.

(2) How the proposed plan will achieve the specific goals of the Shared Savings Program.

(3) How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(e) *Selection of track and option for interim payment calculation.*

(1) As part of its application, an ACO must specify whether it is applying to participate in Track 1 or Track 2 (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay losses for which it may be liable, and any other monies determined to be owed upon first performance year reconciliation.

(i) As part of its application, an ACO that is applying to participate under the two-sided model of the Shared Savings Program or requesting an interim payment calculation under the one-sided model must submit for CMS approval documentation that it is capable of repaying losses or other monies determined to be owed upon first year reconciliation.

(ii) The documentation specified in paragraph (f)(1)(i) of this section must include details supporting the adequacy of the mechanism for repaying losses, or other monies determined to be owed upon first year reconciliation,

equal to at least 1 percent of the ACO's total per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark.

(2) An ACO may demonstrate its ability to repay losses, or other monies determined to be owed upon first year reconciliation, by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing another appropriate repayment mechanism that will ensure its ability to repay the Medicare program.

(3) An ACO participating under the two-sided model must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application on the basis of the information contained in and submitted with the application.

(2) CMS notifies applicant ACOs when the application is incomplete and provide an opportunity to submit information to complete the application. Applications remaining incomplete by the application due date will be denied.

(b) *Notice of determination.* (1) CMS notifies in writing each applicant ACO of its determination to approve or deny the ACO's application to participate in the Shared Savings Program.

(2) If CMS denies the application, the notice will indicate that the ACO is not qualified to participate in the Shared Savings Program, specify the reasons why the ACO is not so qualified, and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

§ 425.208 Provisions of participation agreement.

(a) *General rules.* (1) Upon being notified by CMS of its approval to participate in the Shared Savings Program, an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement.

(2) Under the participation agreement the ACO must agree to comply with the provisions of this part in order to participate in the Shared Savings Program.

(b) *Compliance with laws.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree, or to comply with all applicable laws including, but not limited to, the following:

(1) Federal criminal law.

(2) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(3) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(4) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(5) The physician self-referral law (42 U.S.C. 1395nn).

(c) *Certifications.* (1) The ACO must agree, as a condition of participating in the program and receiving any shared savings payment, that an individual with the authority to legally bind the ACO will certify the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, including, but not limited to, the application form, participation agreement, and any quality data or other information on which CMS bases its calculation of shared savings payments and shared losses.

(2) Certifications must meet the requirements at § 425.302.

§ 425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.

(a) The ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance.

(b) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of this part, including, but not

limited to, those specified in the participation agreement with CMS.

§425.212 Changes to program requirements during the agreement term.

(a)(1) ACOs are subject to all statutory changes that become effective during the term of their participation agreement.

(2) ACOs are subject to all regulatory changes with the exception of the following program areas:

(i) Eligibility requirements concerning the structure and governance of ACOs.

(ii) Calculation of sharing rate.

(iii) Beneficiary assignment.

(b) In those instances where there are changes in law or regulations, the ACO will be required to submit to CMS for review and approval, as a supplement to its original application, an explanation detailing how it will modify its processes to address these changes in law or regulations.

(c) If an ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP. If the ACO fails to effectuate the necessary modifications while under the CAP, the ACO will be terminated from the Shared Savings Program using the procedures in §425.218.

(d) An ACO will be permitted to terminate its agreement, in those instances where Shared Savings Program statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program.

§425.214 Managing changes to the ACO during the agreement.

(a)(1) During the term of the participation agreement, an ACO may add or remove ACO participants or ACO providers/suppliers (identified by TINs and NPIs).

(2) An ACO must notify CMS within 30 days of such an addition or removal.

(3) The ACO's benchmark, risk scores, and preliminary prospective assignment may be adjusted for this change at CMS' discretion.

(b) ACOs must notify CMS within 30 days of any significant change. A ''significant change'' occurs when an ACO is no longer able to meet the eligibility or program requirements of this Part.

(c) Upon receiving an ACO's notice of a significant change described in paragraph (b) of this section, CMS reevaluates the ACO's eligibility to continue to participate in the Shared Savings Program and may request additional documentation. CMS may make a determination that includes one of the following:

(1) The ACO may continue to operate under the new structure.

(2) The ACO structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application for participation.

(3) The ACO no longer meets the eligibility criteria for the program and its participation agreement must be terminated.

(4) CMS and the ACO may mutually decide to terminate the agreement.

§425.216 Actions prior to termination.

(a) *Pre-termination actions.* (1) If CMS concludes that termination of an ACO from the Shared Savings Program is warranted, CMS may take one or more of the following actions prior to termination of the ACO from the Shared Savings Program.

(i) Provide a warning notice to the ACO regarding noncompliance with one or more program requirements.

(ii) Request a CAP from the ACO.

(iii) Place the ACO on a special monitoring plan.

(2) Nothing in this part, including the actions set forth in paragraph (a)(1) of this section, negates, diminishes, or otherwise alters the applicability of other laws, rules, or regulations, including, but not limited to, the Sherman Act (15 U.S.C. 1 *et seq.*), the Clayton Act (15 U.S.C. 12), and the Federal Trade Commission Act (15 U.S.C. 45 *et seq.*).

(b) *Corrective action plans.* (1) The ACO must submit a CAP for CMS approval by the deadline indicated on the notice of violation.

(i) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or

both correct any deficiencies and comply with all applicable Shared Savings Program requirements.

(ii) The ACO's performance will be monitored and evaluated during and after the CAP process.

(2) CMS may terminate the ACO's agreement if the ACO fails to submit, obtain approval for, or implement a CAP, or fails to demonstrate improved performance upon completion of the CAP.

§ 425.218 Termination of the agreement by CMS.

(a) *General.* CMS may terminate the participation agreement with an ACO when an ACO, the ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under this part.

(b) *Grounds for termination by CMS.* CMS may terminate the participation agreement for reasons including, but not limited to the following:

(1) Non-compliance with eligibility and other requirements described in this part.

(2) The imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agency leading to inability of the ACO to comply with the requirements under this part.

(3) Violations of the physician self-referral prohibition, civil monetary penalties (CMP) law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.

(c) CMS may immediately terminate a participation agreement without taking any of the pre-termination actions set forth in § 425.216.

(d) *Notice of termination by CMS.* CMS notifies an ACO in writing of its decision to terminate the participation agreement.

§ 425.220 Termination of an agreement by the ACO.

(a) *Notice of termination.* An ACO must provide at least 60 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of its termination.

(b) *Payment consequences of early termination.* The ACO will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement.

§ 425.222 Re-application after termination.

(a) An ACO that has been terminated from the Shared Savings Program under § 425.218 or § 425.220 may participate in the Shared Savings Program again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated.

(b) To be eligible to participate in the Shared Savings Program after a previous termination, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

(c) An ACO under the one-sided model whose agreement was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO under the two-sided model whose agreement was terminated may only re-apply for participation in the two-sided model.

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.* (1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements; and

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS.

(b) [Reserved]

§ 425.304 Other program requirements.

(a) *Beneficiary inducements.* (1) ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Consistent with the provisions of paragraph (a)(1) of this section and subject to compliance with all other applicable laws and regulations, ACO, ACO participants and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and the items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(b) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers will be reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity

history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(c) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

(d) *Required reporting of NPIs and TINs.* (1) The ACO must maintain, update, and annually furnish to CMS at the beginning of each performance year and at other such times as specified by CMS the list of each ACO participant's TIN and ACO providers/supplier's NPI that is required to be submitted under § 425.204(c)(5)(i).

(2) The ACO must notify CMS within 30 days of any changes to the list of NPIs and TINs.

§ 425.306 Participation agreement and exclusivity of ACO participant TINs.

(a) For purposes of the Shared Savings Program, each ACO participant TIN is required to commit to a participation agreement with CMS.

(b) Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO for purposes of Medicare beneficiary assignment. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one Medicare Shared Savings Program ACO.

§ 425.308 Public reporting and transparency.

For purposes of the Shared Savings Program, each ACO must publicly report the following information regarding the ACO in a standardized format as specified by CMS:

(a) Name and location.

(b) Primary contact.

(c) Organizational information including all of the following:

(1) Identification of ACO participants.

(2) Identification of participants in joint ventures between ACO professionals and hospitals.

(3) Identification of the members of its governing body.

(4) Identification of associated committees and committee leadership.

(d) Shared savings and losses information, including:

(1) Amount of any shared savings performance payment received by the ACO or shared losses owed to CMS.

(2) Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

(e) Results of patient experience of care survey and claims based measures. Quality measures reported using the GPRO web interface will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

§ 425.310 Marketing requirements.

(a) *File and use.* Marketing materials and activities, as defined in § 425.20, may be used or conducted five business days following their submission to CMS if—

(1) The ACO certifies compliance with all the marketing requirements under this section; and

(2) CMS does not disapprove the marketing materials or activities.

(b) *Deemed approval.* (1) Marketing materials and activities are deemed approved after expiration of the initial 5 day review period specified in paragraph (a) of this section.

(2)(i) CMS may issue written notice of disapproval of marketing materials and activities at any time, including after the expiration of the initial 5 day review period.

(ii) The ACO, ACO participant, ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities as applicable, must discontinue use of any marketing materials or activities disapproved by CMS.

(c) *Marketing requirements.* Marketing materials and activities must meet all of the following:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304(a) regarding beneficiary inducements.

(4) Not be materially inaccurate or misleading.

(d) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

§ 425.312 Notification to beneficiaries of participation in shared savings program.

(a) ACO participants must do all of the following:

(1) Notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program.

(2) Post signs in their facilities to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program.

(3) Make available standardized written notices regarding participation in an ACO and, if applicable, data opt-out. Such written notices must be provided by the ACO participants in settings in which beneficiaries receive primary care services.

(b)(1) ACOs have the option of notifying beneficiaries on the preliminary prospective assignment list and quarterly assignment list provided to the ACO under § 425.704(d).

(2) ACOs choosing this option must use the standardized written notice developed by CMS.

(c) The beneficiary notifications under this section meet the definition of marketing materials and activities under § 425.20 and therefore must meet all applicable marketing requirements described in § 425.310.

§ 425.314 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree, that the CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities that pertain to all of the following:

(1) The ACO's compliance with Shared Savings Program.

(2) The quality of services performed and determination of amount due to or from CMS under the participation agreement.

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(4) If as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due

to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree to the following:

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(c) *Responsibility of the ACO.* Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the requirements set forth in this section.

(d) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

§ 425.316 Monitoring of ACOs.

(a) *General rule.* (1) In order to ensure that the ACO continues to satisfy the eligibility and program requirements under this part, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregate annual and quarterly reports.

(ii) Analysis of beneficiary and provider complaints.

(iii) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, on-site compliance reviews).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* (1) CMS may use one or more of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at §§ 425.216 and 425.218, CMS will take the following actions:

(1) The ACO may be given a warning for the first time it fails to meet the minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(2) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet quality performance standards in the following year, the agreement will be terminated.

(3)(i) If an ACO fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain, CMS will request that the ACO submit—

(A) The required measure data;

(B) Correct the data;

(C) Provide a written explanation for why it did not report the data completely and accurately; or

(D) A combination of the submission requirements in paragraphs (c)(3)(i)(A) through (c)(3)(i)(C) of this section.

(ii) If ACO still fails to report, fails to report by the requested deadline, or does not provide a reasonable explanation for not reporting, the ACO will be terminated immediately.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting of the quality performance measures, or fails to make timely corrections following notice to resubmit, may be terminated.

(5) An ACO will not qualify to share in savings in any year it fails to report fully and completely on the quality performance measures.

Subpart E—Assignment of Beneficiaries

§ 425.400 General.

(a)(1)(i) A Medicare fee-for-service beneficiary is assigned to an ACO when the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2)(i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 months of data.

(iii) Final assignment is determined after the end of each performance year, based on data from the performance year.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS codes, G codes, or revenue center codes as indicated in the definition of primary care services under § 425.20.

§ 425.402 Basic assignment methodology.

(a) CMS employs the following stepwise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a physician who is an ACO provider/supplier of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO providers/suppliers in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by—

(i) All ACO professionals who are ACO providers/suppliers in any other ACO; and

(ii) Other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

(b) [Reserved]

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in § 425.402, with two special conditions:

(a) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(b) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service if the—

(1) NPI of a physician included in the attestation is reported on the claim as the attending provider; and

(2) Claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20.

Subpart F—Quality Performance Standards and Reporting

§ 425.500 Measures to assess the quality of care furnished by an ACO.

(a) *General.* CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings.

(b) *Selecting measures.* (1) CMS selects the measures designated to determine an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(2) CMS designates the measures for use in the calculation of the quality performance standard.

(3) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(c) ACOs must submit data on the measures determined under paragraph (b) of this section according to the method of submission established by CMS.

(d) *Patient experience of care survey.* For performance years beginning in 2014 and for subsequent performance years, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(e) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO.

(1) In an audit, the ACO will provide beneficiary medical records data if requested by CMS.

(2) The audit will consist of three phases of medical record review.

(3) If, at the conclusion of the third audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists.

(f) Failure to report quality measure data accurately, completely, and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, as described in §§ 425.216 and 425.218.

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year.

(1) For the first performance year of an ACO's agreement, CMS defines the quality performance standard at the level of complete and accurate reporting for all quality measures.

(2) During subsequent performance years, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the minimum attainment level of certain measures.

(b) *Establishing a performance benchmark and minimum attainment level for measures.* (1) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures.

(2) Contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage.

(3) The minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark.

(c) *Methodology for calculating a performance score for each measure.* (1) Performance below the minimum attainment level for a measure will receive zero points for that measure.

(2) Performance equal to or greater than the minimum attainment level for a measure will receive points on a sliding scale based on the level of performance.

(3) Those measures designated as all or nothing measures will receive the maximum available points if all criteria are met and zero points if one or more of the criteria are not met.

(4) Performance at or above 90 percent or the 90th percentile of the performance benchmark earns the maximum points available for the measure.

(d) *Establishing quality performance requirements for domains.* (1) CMS groups

individual quality performance standard measures into four domains:

(i) Patient/care giver experience.

(ii) Care coordination/Patient safety.

(iii) Preventative health.

(iv) At-risk population.

(2) To satisfy quality performance requirements for a domain:

(i) The ACO must report all measures within a domain.

(ii) ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions describe in § 425.216(c).

(iii)(A) If the ACO achieves the minimum attainment level for at least one measure in each of the four domains, and also satisfies the requirements for realizing shared savings under subpart G of this part, the ACO may receive the proportion of those shared savings for which it qualifies.

(B) If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated.

(e) *Methodology for calculating the ACO's overall performance score.* (1) CMS scores individual measures and determines the corresponding number of points that may be earned based on the ACO's performance.

(2) CMS adds the points earned for the individual measures within the domain and divides by the total points available for the domain to determine the domain score.

(3) Domains are weighted equally and scores averaged to determine the ACO's overall performance score and sharing rate.

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.

(a) *Physician quality reporting system.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of receiving an incentive payment under the Physician Quality Reporting System.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under Subpart F of this part during the reporting period according to the method of submission established by CMS under the Shared Savings Program in order to receive a Physician Quality Reporting System incentive under the Shared Savings Program.

(3) If ACO providers/suppliers who are eligible professionals within an ACO qualify for a Physician Quality Reporting System incentive payment, each ACO participant TIN, on behalf of its ACO supplier/provider participants who are eligible professionals, will receive an incentive, for those years an incentive is available, based on the allowed charges under the Physician Fee Schedule for that TIN.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a Physician Quality Reporting System incentive outside of the Medicare Shared Savings Program.

(5) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

(b) [Reserved]

§ 425.506 Electronic health records technology.

(a) ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure.

(b) As part of the quality performance score, the quality measure regarding EHR adoption will be measured based on a sliding scale.

(c) Performance on this measure will be weighted twice that of any other measure for scoring purposes and for determining compliance with quality performance requirements for domains.

Subpart G—Shared Savings and Losses

§ 425.600 Selection of risk model.

(a) For its initial agreement period, an ACO may elect to operate under one of the following tracks:

(1) *Track 1.* Under Track 1, the ACO operates under the one-sided model (as described under § 425.604 of this part) for the agreement period.

(2) *Track 2.* Under Track 2, the ACO operates under the two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(b) For subsequent agreement periods, an ACO may not operate under the one-sided model.

(c) An ACO experiencing a net loss during the initial agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period.

§ 425.602 Establishing the benchmark.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* In computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year in order to minimize variation from catastrophically large claims.

(5)(i) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(ii) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures in BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) The ACO's benchmark may be adjusted for the addition and removal of ACO participants or ACO providers/suppliers during the term of the agreement period.

(b) *Updating the benchmark.* CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(1) CMS updates this fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary.

(2) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Resetting the benchmark.* An ACO's benchmark will be reset at the start of each agreement period.

§ 425.604 Calculation of savings under the one-sided model.

(a) *Savings determination.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are below the applicable updated benchmark determined under § 425.602.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust for changes in the continuously assigned population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust for changes in severity and case mix in this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a). In adjusting for health status and demographic changes CMS makes adjustments for separate categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings rate (MSR).* CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for an ACO participating under the one-sided model. The MSR under the one-sided model for an ACO based on the number of assigned beneficiaries is as follows:

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0	

(c) *Qualification for shared savings payment.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the one-sided model may not exceed 10 percent of its updated benchmark.

(f) *Notification of savings.* CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

§ 425.606 Calculation of shared savings and losses under the two-sided model.

(a) *General rule.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are above or below the updated benchmark determined under § 425.602. In order to qualify for a shared savings payment under the two-sided model, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust for changes in the continuously assigned beneficiary population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust for changes in severity and case mix for this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a). In adjusting for health status and demographic changes CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) To qualify for shared savings under the two-sided model, an ACO's average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least 2 percent.

(2) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be at least 2 percent above its updated benchmark costs for the year.

(c) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the two-sided model will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the two-sided model may not exceed 15 percent of its updated benchmark.

(f) *Shared loss rate.* The shared loss rate—

(1) For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in § 425.606(d) (that is, 1 minus the final shared savings rate determined under § 425.606(d) of this part); and

(2) May not exceed 60 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark as determined under § 425.602:

(1) 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program.

(2) 7.5 percent in the second performance year.

(3) 10 percent in the third and any subsequent performance year.

(h) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

§ 425.608 Determining first year performance for ACOs beginning April 1 or July 1, 2012.

(a) For April 1 and July 1, 2012 starters, first year (defined as 21 and 18 months respectively) performance will be based on an optional interim payment calculation (based on the ACO's first 12 months of participation) and a final reconciliation at the end of the ACO's first performance year. Unless stated otherwise, for purposes of the interim payment calculation and first year reconciliation, the methodology under subpart E of this part for assigning beneficiaries and the methodology described in § 425.602 through § 425.606 for calculating shared savings and losses will apply, and quality performance will be assessed as described in subpart F of this part.

(b) In the interim payment calculation, based on the ACO's first 12 months of performance—

(1) CMS compares the first 12 months of per capita beneficiary expenditures to a historical benchmark updated for the period which includes the ACO's first 12 months of participation, taking into account changes in health status and demographics; and

(2) Quality performance is based on GPRO quality data reported for CY 2012.

(c)(1) The interim payment calculation is reconciled with the ACO's performance for its complete first performance year, defined as 21 months for April 1, 2012 starters and 18 months for July 1, 2012 starters.

(2) The first year reconciliation takes into account expenditures spanning the entire 21 or 18 months of the first performance year.

(3) First performance year expenditures are summed over beneficiaries assigned in two overlapping 12 month assignment windows.

(i) The first window will be the first 12 months used for interim payment calculation.

(ii) The second window will be CY2013.

(4) Expenditures for the first performance year are the sum of aggregate expenditure dollars accounting for the ACO's first 6 or 9 months of performance within CY 2012 for beneficiaries assigned for the interim payment calculation and aggregate dollars calculated for CY2013 for beneficiaries assigned for CY 2013.

(5) Adjustments for health status and demographic changes are performed as described in § 425.604 through § 425.606 with the following exceptions:

(i) Beneficiaries from the CY2013 assignment window are identified as continuously assigned or newly assigned relative to the previous calendar year.

(ii) The adjustment factor identified for purposes of the interim payment calculation is applied to the 6 months or 9 months of the ACO's first performance year that lie within CY2012.

(6) The updated benchmark, stated in aggregate dollars, is the sum of the interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012 and an updated aggregate benchmark representing CY 2013.

(7) A savings percentage (based on a comparison of summed expenditures to summed updated benchmark dollars) for the ACO's 18 or 21 month performance year is compared to the ACO's MSR or MLR. The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year is net of any interim payments of shared savings or losses.

(8) Quality performance for the first year reconciliation is based on complete and accurate reporting, of all required quality measures, for CYs 2012 and 2013.

(d) An ACO with a start date of April 1, 2012 or July 1, 2012 has the option to request an interim payment calculation based on quality and financial performance for its first 12 months of program participation. As required under § 425.204(f), the ACO requesting an interim payment calculation must have a mechanism in place to pay back the interim payment if final reconciliation determines an overpayment.

(e) Unless otherwise stated, program requirements which apply in the course of a performance year apply to the interim payment calculation and first year reconciliation.

Subpart H—Data Sharing With ACOs

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.702 Aggregate reports.

CMS shares aggregate reports with ACOs as follows:

(a) Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

(b) These aggregate reports include, when available, the following information, deidentified in accordance with 45 CFR 164.514(b):

(1) Aggregated metrics on the assigned beneficiary population.

(2) Utilization and expenditure data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c)(1) At the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, process development, case management, and care coordination, will provide the ACO with information regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports under paragraphs (a) and (b) of this section. The information includes the following:

(i) Beneficiary name.

(ii) Date of birth.

(iii) HICN.

(iv) Sex.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

(i) As a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) As the business associate of its ACO participants and ACO providers/suppliers, who are HIPAA-covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

§ 425.704 Beneficiary-identifiable data.

Subject to providing the beneficiary with the opportunity to decline data sharing as described in this § 425.708, and subject to having a valid DUA in place, CMS, upon the ACO's request for the data for purposes of evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, will provide the ACO with beneficiary identifiable claims data for preliminary prospective assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based during the agreement period.

(a) If an ACO wishes to receive beneficiary identifiable claims data, it must sign a DUA and it must submit a formal request for data. ACOs may request data as often as once per month.

(b) The ACO must certify that it is requesting claims data about either of the following:

(1) Its own patients, as a HIPAA-covered entity, and the request reflects

the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(2) The patients of its HIPAA-covered entity ACO participants or its ACO providers/suppliers as the business associate of these HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(c) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(d) To ensure that beneficiaries have a meaningful opportunity to decline having their claims data shared with the ACO, the ACO may only request claims data about a beneficiary if—

(1) The beneficiary name appears on the preliminary prospective assignment list found on the initial or quarterly aggregate report, or has received primary care services from an ACO participant upon whom assignment is based (under Subpart E of this part), during the agreement period.

(2) The beneficiary has been notified in writing how the ACO intends to use beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in § 425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under § 425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in § 425.710 is a condition of an ACO's participation in the Shared Savings Program.

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Procedure code.
(3) Gender.
(4) Diagnosis code.
(5) Claim ID.
(6) The from and through dates of service.
(7) The provider or supplier ID.
(8) The claim payment type.
(9) Date of birth and death, if applicable.
(10) TIN.
(11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Prescriber ID.
(3) Drug service date.
(4) Drug product service ID.
(5) Quantity dispensed.
(6) Days supplied.
(7) Brand name.
(8) Generic name.
(9) Drug strength.
(10) TIN.
(11) NPI.
(12) Indication if on formulary.
(13) Gross drug cost.

§ 425.708 Beneficiaries may decline data sharing.

(a) Before requesting claims data about a particular beneficiary, the ACO must inform the beneficiary that it may request personal health information about the beneficiary for purposes of its care coordination and quality improvement work, and give the beneficiary meaningful opportunity to decline having his/her claims information shared with the ACO.

(b) ACOs may contact preliminarily prospective assigned beneficiaries. in writing to request data sharing.

(1) If these beneficiaries do not decline within 30 days after the letter is sent, the ACO may request identifiable claims data from CMS.

(2) These beneficiaries must also be provided a form explaining the beneficiary's opportunity to decline data sharing as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(c) For beneficiaries that have a primary care service office visit with an ACO participant who provides primary care services, the ACO must supply the beneficiaries with a written notification explaining their opportunity to decline data sharing. The form must be provided to each beneficiary as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(d) The requirements specified in paragraphs (a) through (c) of this section do not apply to the initial identifiable data points that CMS provides to ACOs under § 425.702(d).

(e) CMS does not share beneficiary identifiable claims data relating to treatment for alcohol and substance abuse in accordance with 42 CFR 290dd–2 and the implementing regulations at 42 CFR part 2.

(f) The provisions of this section relate only to the sharing of Medicare claims data between the Medicare program and the ACO under the Shared Savings Program and are in no way intended to impede existing or future data sharing under other authorities.

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise noncompliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process

§ 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under § 425.500 and § 425.502.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under § 425.602, § 425.604, and § 425.606.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under § 425.604 and 425.606.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.502.

(b) [Reserved]

§ 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review may be held orally (that is, in person, by telephone or other electronic means) or on the record (review of submitted documentation) at the discretion of the reconsideration official.

(b) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

§ 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) Date, time, and location of the review.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Time and place of hearing.* The reconsideration official may, on his or her own motion, or at the request of CMS or the ACO, change the time and place for the reconsideration review, but must give CMS and the ACO notice of the change.

(e) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(f) The reconsideration official will notify CMS and the ACO of his or her recommendation.

§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

§ 425.808 Effect of independent CMS official's decision.

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

§ 425.810 Effective date of decision.

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS ment published at 77 FR 29028, May 16, 2012.

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

SOURCE: 68 FR 63716, Nov. 7, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 426.100 Basis and scope.

(a) *Basis*. This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope*. This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

§ 426.110 Definitions.

For the purposes of this part, the following definitions apply:

Aggrieved party means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

Board means the Departmental Appeals Board.

Clinical and scientific experts mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

Deemed NCD means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

New evidence means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

Party means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

Proprietary data and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5

of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.65.

(2) The party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked proprietary is not considered proprietary.

Reasonableness standard means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Supplemental LCD/NCD record is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

Treating physician means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

§ 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

§ 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

Subpart B [Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

§ 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

§ 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

§ 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign

rights to request review under section 1869(f) of the Act.

§ 426. 325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;

(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M+C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

§ 426.330 Burden of proof.

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

§ 426.340 Procedures for review of new evidence.

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(2) Sets a reasonable timeframe—

(i) For LCDs, of not more than 90 days, by which the contractor completes the reconsideration; or

(ii) For NCDs, in compliance with the timeframes specified in section 1862(1) of the Act, by which CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) Does not meet—

(i) For LCDs, the 90-day reconsideration timeframe; or

(ii) For NCDs, the reconsideration timeframe specified by the Board, in compliance with section 1862(l) of the Act.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

[68 FR 63716, Nov. 7, 2003, as amended at 70 FR 70335, Nov. 21, 2005; 71 FR 9461, Feb. 24, 2006]

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp.*

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in any way with the ALJ on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the ALJ assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the

complaint and informing the aggrieved party (or parties) of the docket number and the deadline for the contractor to produce the LCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to the applicable contractor and CMS.

(3) Requires CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation*. If a review is pending regarding a particular LCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the ALJ consolidates the complaints and conducts a consolidated LCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same LCD or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the ALJ's decision.

(2) *Decision to consolidate complaints*. If an ALJ decides to consolidate complaints, the ALJ does the following:

(i) Provides notification that the LCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints*. If an ALJ decides not to consolidate complaints, the ALJ conducts separate LCD reviews for each complaint.

[68 FR 63716, Nov. 7, 2003; 68 FR 65346, Nov. 19, 2003]

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340, within such deadline as the ALJ may set.

§ 426.418 LCD record furnished to aggrieved party.

(a) *Elements of a contractor's LCD record furnished to the aggrieved party*. Except as provided in paragraph (b) of this section, the contractor's LCD record consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD being challenged.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or

other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the LCD record not furnished to the aggrieved party*. The LCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

(a) Documents included in § 426.418(a).

(b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

(1) Retiring an LCD or LCD provision that is under review; or

(2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

(1) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has retired the LCD or revised the LCD to completely remove the provision in question, the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provision(s).

(2) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has revised the LCD provision in question but has not removed it altogether, the ALJ must continue the review based on the revised LCD. In this case, the contractor must send a copy of the supplemental record to the ALJ and all parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD*. An aggrieved party who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an LCD*. To withdraw a complaint regarding an LCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the ALJ (see § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party*. If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints*. If the ALJ receives a notice

from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews.* If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid.* Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response.* The contractor has 30 days after receiving the aggrieved party's statement to submit a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation.* (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§ 426.432 and 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps.* To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provison(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps.* The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

§ 426.432 Discovery.

(a) *General rule.* If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order.* The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents.* For the purpose of this section, the term ''documents'' includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data.* The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a pre-hearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (See § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (See § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

(a) A written decision, including a description of appeal rights.

(b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings.* An ALJ's decision must include one of the following:

(1) A determination that the provision of the LCD is valid under the reasonableness standard.

(2) A determination that the provision of the LCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.

(4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information.* An ALJ's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS or its contractors to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.

(f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the ALJ's LCD review record consists of any document or material that the ALJ compiled or considered during the LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal

that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M+C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M+C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M+C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1) of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review*—(1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

(1) A statement upholding the part(s) of the ALJ decision named in the appeal.

(2) A statement reversing the part(s) of the ALJ decision named in the appeal.

(3) A statement modifying the part(s) of the ALJ decision named in the appeal.

(4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

(b) *Other information.* A Board decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the review of the ALJ decision.

(3) A summary of the ALJ's decision.

(4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.

(f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(7) The Board's decision.

(b) *Elements of the Board's LCD appeal record furnished to the court under seal.* The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M+C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M+C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

(1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last known address, the contractor, and CMS of the Board's remand decision; and

(2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review.

Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

(1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) Email address, if applicable.

(2) *If the beneficiary has a representative,* the representative's indetifying information must include the following:

(i) Name.

(ii) Address.

(iii) Telephone number.

(iv) E-mail address (if any)

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

(i) Title of NCD being challenged.

(ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written complaint with the Board if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on its own motion, concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceeding in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in this regulation.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an NCD review for failure to comply with a Board order or procedural request without good cause.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

(3) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

(7) Conduct an NCD review of any policy that is not an NCD, as defined in § 400.202 of this chapter.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his or her representative;

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae*.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

(14) Find invalid applicable Federal statutes, regulations, or rulings.

(15) Enter a decision specifying terms to be included in an NCD.

§ 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.510 Docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint.* The Board does the following upon receiving a complaint regarding an NCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular NCD; or

(ii) Related to a pending NCD review.

(3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint.* The Board determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for condideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

(i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;

(ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;

(iii) Participation does not result in substantial delay; and

(iv) The petition for participation meets the criteria in § 426.513.

§ 426.513 Participation as *amicus curiae.*

(a) *Petition for participation.* Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

(1) The petitioner's interest in the hearing;

(2) Who will represent the petitioner; and

(3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation.* An *amicus curiae* is not a party to the hearing but may participate by—

(1) Submitting a written statement of position to the Board before the beginning of the hearing;

(2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in §§ 426.510(f)(3) and 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

(1) Submitted with the initial complaint;

(2) Submitted with an amended complaint;

(3) Produced during discovery;

(4) Produced when the Board consults with scientific and clinical experts; and

(5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party*. Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

(1) The NCD being challenged.

(2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party*. The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the

review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (see § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

§ 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the NCD ends the review process.

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an NCD record has been supplemented, except that discovery and the taking of evidence is not repeated. The period for the aggrieved party to file a statement begins when

the aggrieved party receives the supplement.

§ 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps.* The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

(1) Confine the NCD review to the provision(s) of the NCD raised in the aggrieved party's complaint.

(2) Conduct a hearing unless the matter can be decided on the written record.

(3) Close the NCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps.* The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

§ 426.532 Discovery.

(a) *General rule.* If the Board orders discovery, the Board must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The Board granting of a protective order.* The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Will unduly delay the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific NCD.

(d) *Types of documents.* For the purpose of this section, the term documents includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information or proprietary data.* The Board must not under any circumstances order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The Board notifies all parties in writing when the discovery period will be closed.

§ 426.535 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by witnesses or documents and state whether those facts could be established by evidence other than by the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written

motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

(2) Include the docket number and title of the NCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the Board a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.540 Evidence.

(a) Except as provided in this part, the Board is not bound by the Federal Rules of Evidence. However, the Board may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

(c) The Board may accept privileged information or proprietary data, but must maintain it under seal.

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

§ 426.544 Dismissals for cause.

(a) The Board may, at the request of any party, or on its own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the prehearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the Board without cause shown.

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (See § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (See § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

§ 426.545 Witness fees.

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.547 Issuance, notification, and posting of a Board's decision.

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's decision.

(a) *Findings.* The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information.* The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

§ 426.555 Prohibited provisions of the Board's decision.

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment,

coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

§ 426.557 Optional provisions of the Board's decision.

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

§ 426.560 Effect of the Board's decision.

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M+C organization, or other Medicare managed care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an M+C organization, or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M+C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief.* Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

§ 426.562 Notice of the Board's decision.

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.563 Future new or revised or reconsidered NCDs.

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as additional evidence) than what the Board evaluated.

§ 426.565 Board's role in making an LCD or NCD review record available.

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

§ 426.566 Board decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

§ 426.587 Record for appeal of a Board NCD decision.

(a) *Elements of the Board's NCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered during an NCD review, including, but not limited to, the following:

(1) The NCD complaint.

(2) The NCD and NCD record.

(3) The supplemental NCD record, if applicable.

(4) Transcripts of record.

(5) Any other evidence relevant gathered under § 426.540.

(6) The Board's decision.

(b) *Documents excluded from the NCD review record furnished to the court.* The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.

FINDING AIDS

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423.464 (f)(1)(vii) and (viii) revised; (f)(1)(ix), (5) and (6) added 20507
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423.505 (h)(1) revised 20507
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423.570 (d)(3) revised 20507
423.584 (b)(3) added 20507
423.610 (c)(2) revised 20507
423.756 (d)(3) correctly added 55764
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423.902 Amended 20509

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423.2260—423.2276 (Subpart V) Added 54222
423.2268 (b), (g), (h), (n) and (q) added; interim 54253
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423.2274 Added; interim 54253
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424.36 (b)(6)(ii)(C)(*2*) corrected 2432
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424.44 (a) introductory text revised; (e) added 69939
424.57 (a) amended; (f) added 69939
424.502 Amended 69939
424.510 (d)(2)(iv) and (e) added 36461
424.516 Added 69939
424.517 Added 69940
424.520 Revised 69940
424.521 Added 69940
424.525 (a)(1), (2) and (b) revised 36461
424.530 Heading revised; (a)(6) and (7) added 69940
424.535 (c) through (f) redesignated as (d) through (g); (a)(8) and new (c) added 36461
(a)(1) amended; (a)(9), (10) and (g) added; (f) revised 69940
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414.61 Added 62006
414.65 (a)(1) revised 62006
414.68 Added 62006
414.210 (e)(2) revised; (e)(5) added 62009
414.402 Amended; interim 2880, 62009
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414.404 (b)(1) introductory text, (ii) and (iii) revised; interim 2880

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414.414 (c) and (d) revised; interim 2880
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414.422 (f) redesignated as (g); new (f) added; interim 2881
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414.425 Added 62011
414.610 (c)(5)(i) revised 62012
414.802 Amended 62012
414.904 (d)(3) amended 62012
414.906 (c)(2) redesignated as (c)(3); (c) introductory text, new (2), new (3) heading, (f)(2)(v), (3)(iv) and (g) added; (c)(1) revised 62012
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414.914 (f)(12) revised 62013
414.916 (b)(4) redesignated as (b)(5); new (b)(4) added 62013
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414.930 (a) revised; (b)(1)(v) redesignated as (b)(1)(vi); new (b)(1)(v) added 62013
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418.2 Revised 39413
418.22 (b)(3) added 39413
418.76 (f)(1) revised 39413
418.100 (f)(1)(iii) revised 39413
418.108 (b)(1)(ii) amended 39413
418.200 Revised 39413
418.202 (f) and (g) revised 39413
418.204 (a) revised 39413
418.302 (b)(2) and (f)(2) revised 39414
418.311 Revised 39414
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419.64 (a)(4)(iii) and (iv) added 60680
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422.4 (a)(1)(iv) revised 1541
422.52 (f) revised 1541
422.60 (g) added 1541
422.74 (d)(1) introductory text revised; (d)(1)(iv) added 1541
422.101 (f)(2) added 1541
422.103 (e) added 1541
422.262 (g) and (h) added 1541
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422.504 (g)(1) revised 1542
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422.583 Revised 1542
422.760 (b)(2) and (3) redesignated as (b)(3) and (4); new (b)(2) added 1542
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423.34 (d)(1) revised; (d)(3) added 1543
423.44 (d)(1) introductory text revised; (d)(1)(iv) added 1543
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423.104 (g)(1) revised 1544
423.120 (b)(2) introductory text and (i) revised; (b)(2)(v) added; interim 2888
423.128 (e)(6) revised 1544
423.293 (a)(4) and (e) added 1544
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423.329 (d)(2)(i) revised 1545
423.505 (j)(5) revised 1545
423.507 (a)(2)(ii), (iii), (b)(2)(ii) and (iii) revised 1545
423.551 (g) added 1546
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423.560 Amended 1546
423.562 (b)(4)(iv), (v) and (vi) amended 65363
423.564 (d)(2), (e)(1) and (2) amended 65363
423.566 (c)(3) revised 1546
423.568 (a) revised 1546
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423.572 (a) revised 1546
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423.590 (d)(1), (e) and (f)(2) revised 1548
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423.612 Removed 65363
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423.630 Removed 65363
423.634 Removed 65363
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424.22 (a)(1)(i) and (b)(2) revised 58133
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414.408 (f)(1) revised; (h)(2) through (7) redesignated as (h)(3) through (8); new (h)(2) added; new (h)(3)(i) and (ii) amended 73623
414.410 (a)(2) and (3) revised; (a)(4) added 73623
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414.422 (e)(3) added 73623
414.423 Added 73623
414.610 (c)(1)(i), (5)(ii), (f) and (h) revised; (c)(1)(ii) redesignated as (c)(1)(iii); new (c)(1)(ii) added 73625
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417.644 Removed 19803
417.646 Removed 19803
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417.692 Removed 19803
417.694 Removed 19803
417.840 Revised 19803
418.22 (a)(3) and (b)(3)(iii) revised; (a)(4), (b)(3)(v), (4) and (5) added 70463
419 Technical correction 45700
419.21 (e) revised 72265
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419.43 (c) revised 72265
419.70 (d)(2) introductory text revised; (d)(6) added 72265
422.2 Amended 19803
422.4 (a)(1)(v) and (2)(i)(A) revised; (a)(2)(i)(B) redesignated as (a)(2)(i)(C); new (a)(2)(i)(B) and (3)(iv) added 19804
422.74 (d)(1)(i)(B) and (4)(iii) revised 19804
422.100 (f) introductory text revised; (f)(1) and (2) amended; (f)(4), (5) and (6) amended 19804
422.103 (d)(3) added 19805
422.105 (b), (c) and (f) revised 19805
422.108 (b)(3) revised 19805
422.111 (g) added 19805
422.112 (a)(10) added 19805

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422.152 (a)(1) and (2) revised; (b)(3)(ii), (e)(2)(ii) and (iii) redesignated as (b)(3)(iii), (e)(e)(2)(iii) and (iv); new (b)(3)(ii), (5) and (e)(2)(ii) added 19805
422.153 Added 19806
422.156 (b)(7) and (f) revised 19806
422.254 (a)(4) and (b)(5) added 19806
422.256 (b)(4) added 19806
422.304 (f) added 44564
422.306 (a) revised 19806
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422.501 (b) through (e) redesignated as (c) through (f); new (b) added; new (c)(1) introductory text and (2) revised 19809
422.502 (a)(1), (2), (b) and (c)(3)(iii) revised; (c)(2)(iii) added; (d) removed 19809
422.503 (b)(4)(vi) revised; (b)(7) added 19809
422.504 (e)(1)(ii) and (iii) redesignated as (e)(1)(iii) and (iv); new (e)(1)(ii) and (m) added; new (e)(1)(iii) and (i)(2)(i) revised 19810
422.506 (a)(2)(ii), (3)(i), (b)(2)(ii) and (3) revised; (a)(2)(iii) and (b)(2)(iii) removed; (b)(1)(iv) added 19811
422.508 (c) added 19811
422.510 (a), (b) introductory text, (2)(i) and (c) revised; (b)(2)(ii) and (iii) redesignated as (b)(2)(iii) and (iv); new (b)(2)(ii) added 19811
422.516 Heading revised; (g) added 19812
422.561 Amended 19812
422.566 (b)(4) revised; (b)(5) redesignated as (b)(6); new (b)(5) added; (c)(1)(i) and (2)(i) amended 19812
(b)(5) and (6) correctly removed; (c)(2)(i) correctly amended 32859
422.568 (a) through (f) redesignated as (b) through (g); new (a) added; new (d) revised 19812

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422.622 (f)(3) revised 19812
422.624 (c)(1) revised 19812
422.626 (e)(5) and (f) redesignated as (f) and (g); new (f) revised 19812
422.644 (c) revised 19813
422.660 Revised 19813
422.662 (a) and (b) revised 19813
422.664 (b)(2) revised 19813
422.670 Revised 19813
422.676 (d) revised 19813
422.682 Revised 19813
422.692 (a) and (c) revised 19813
422.696 Heading and (a) heading revised 19814
422.750 (a) revised 19814
422.752 (a) introductory text, (1), (3) and (4) revised 19814
422.756 (c) removed; (d), (e) and (f) redesignated as new (c), (d) and (e); (b) and new (c)(1) and (3) revised 19814
422.2260 Amended 19814
422.2262 Heading, (a)(1) and (b) revised; (c) and (d) added 19814
423.34 Revised 19815
423.38 (c)(4) revised 19816
423.44 (d)(1)(iii), (iv) and (5) introductory text redesignated as (d)(1)(iv), (v) and (5)(i); new (d)(1)(iii) and (5)(ii) added 19816
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423.128 (f) added 19818
423.132 (c) introductory text and (d) revised; (c)(2), (3) and (4) amended; (c)(5) redesignated as (c)(6); new (c)(5) added 19818
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(d)(1)(vii)(B) corrected 32860
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423.165 (b)(4) removed; (f) revised 19818
423.265 (b) revised 19818
423.272 (b)(3) added 19819
423.308 Amended 19819
423.462 Existing text designated as (a); new (a) heading and (b) added 19819
423.464 (a)(3), (e)(1)(vi), (g) and (h) added 19819
423.466 Added 19819
423.502 (b), (c) and (d) redesignated as (c), (d) and (e); new (b) added; new (c)(1) introductory text and (2) revised 19819
423.503 (a)(1), (2), (b) and (c)(3)(iii) revised; (c)(2)(iii) added; (d) removed 19820
423.504 (b)(4)(vi) revised; (b)(6) redesignated as (b)(7); new (b)(6) added 19820
423.505 (e)(1)(ii) and (iii) redesignated as (e)(1)(iii) and (iv); new (e)(1)(ii) and (n) added; new (e)(1)(iii), (f)(3) introductory text, (i)(2)(i) and (m)(1)(iii)(C) revised 19821
423.507 (a)(2)(ii), (b)(2)(ii) and (3) revised; (a)(2)(iii) and (b)(2)(iii) removed; (b)(1)(iii) added; (b)(2)(iv) redesignated as new (b)(2)(iii) and amended 19821
423.508 (e) added 19821
423.509 (a), (b) introductory text, (2)(i) and (c) revised; (b)(2)(ii) and (iii) redesignated as (b)(2)(iii) and (iv); new (b)(2)(ii) added 19822
423.514 Heading revised; (g) added 19822
423.551 (g) added 19822
(g) correctly revised 32860
423.568 Revised 19823
423.570 (d)(1) revised 19823
423.572 (b) and (c) revised 19823
423.590 (d)(2) redesignated as (d)(3); new (d)(2) and (h) added; (g) introductory text revised 19823
423.642 (c) revised 19823
423.650 Revised 19824
423.651 (a) and (b) revised 19824
423.652 (b)(2) revised 19824

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423.655 Revised 19824
423.658 (d) revised 19824
423.661 Revised 19824
423.666 (a) and (c) revised 19824
423.668 Heading and (a) heading revised 19824
423.750 (a) revised 19824
423.752 (a) introductory text, (1), (3) and (4) revised 19825
423.756 (c) removed; (d), (e) and (f) redesignated as new (c), (d) and (e); (b) and new (c)(1) and (3) revised 19825
423.773 (c)(2) revised 19825
423.800 (e) added 19825
423.2260 Amended 19825
423.2262 (a)(1)(i) revised; (c) and (d) added 19826
424 Technical correction 60640
424.20 (e)(2) revised 73626
424.22 (a)(1)(v) added; (a)(2), (b)(1) and (d) revised 70463
424.44 (a), (b) and (e) revised 73627
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424.507 Added; interim 24448
424.510 (c) amended 50418
(d)(9) added 70464
(d)(2)(iii) revised 73628
424.516 (f) revised; interim 24449
(e)(3) added 73628
424.520 (a) amended 50418
424.530 (a)(8) added 70464
424.535 (a)(10) revised; interim 24449
(a)(11) added 70465
424.550 (b)(1) and (2) added 70465
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414 Technical correction 1670
414.22 (b)(5)(i)(A), (B) and (C) revised 73471
414.65 (a)(1) introductory text amended 73471

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414.90 (f)(2) removed; (c)(2)(i), (ii), (iii), (f)(3), (g)(4) and (5) redesignated as (c)(4)(i), (ii), (iii), new (f)(2), (g)(5) and (6); (c)(4) introductory text and new (g)(4) added; (b), (c)(2) introductory text, new (f)(2)(ii), (iii) and new (g)(5) amended; (f)(1), new (2) introductory text, (g)(1), (3), new (6), (i)(1) introductory text and (2) introductory text revised 73471

414.92 (c)(2)(ii) revised; eff. 10–6–11 54968

(b), (c)(2) introductory text, (ii) introductory text, (d) introductory text, (1), (2) introductory text and (e)(2)(ii) amended; (c)(2)(ii)(A) through (F) and (f) redesignated as (c)(2)(ii)(A)(*1*) through (*6*) and (g); (c)(2)(ii)(A) introductory text, (B), (iii) and new (f) added 73472

414.202 Amended 70314

414.402 Regulation at 74 FR 2880 confirmed; amended 70314

414.404 Regulation at 74 FR 2880 confirmed; (b)(1) introductory text, (ii) and (iii) revised 70314

414.408 Regulation at 74 FR 2880 confirmed; (e)(2)(iv) revised 70315

414.410 Regulation at 74 FR 2880 confirmed; (a)(1), (2) and (3) revised 70315

414.414 Regulation at 74 FR 2880 confirmed; (c) and (d) revised 70315

414.422 Regulation at 74 FR 2881 confirmed; (f) revised 70315

414.610 (c)(1) introductory text, (ii), (5)(ii) and (h) revised 70315

414.802 Amended 73473

414.904 (d)(3) revised 73473

415 Technical correction 1670

415.130 (d)(1) and (2) amended 73473

416 Technical correction 13292

416.50 (a)(1)(ii), (2) introductory text, (i), (ii), (iii), (a)(3), (b), (c) and (d) redesignated as new (b), (c) introductory text, (1), (2), (3), (d), (e), (f) and (g); new (c)(1) amended; introductory text, (a), new (b), (d) and (e) revised 65889

416.166 (b) revised 74582

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416.171 (b) and (d) revised 74582

416.173 Revised 74582

417.402 (c) introductory text revised 21560

(c)(3) amended; eff. 10–31–11 54633

417.430 (a) heading, (1), (b)(3) and (4) revised 21560

417.454 (d) and (e) added 21561

418.22 (a)(4) and (b)(4) revised 47331

418.202 (g) revised 47331

418.309 Heading, introductory text and (b) revised; (c) and (d) added 47332

419 Technical correction 13292

419.32 (b)(1)(iv)(A) revised; (b)(1)(iv)(B)(1) and (2) amended; (b)(1)(iv)(B)(2) added 74582

419.43 (i) added 74583

419.70 (d)(2) introductory text and (6) revised 74583

422 Technical correction 39006

422.2 Amended 21561

422.4 (a)(1)(iii) and (iv) revised; (a)(1)(vi) added 21561

422.53 Added 21561

422.62 (a)(2)(i), (iii) and (5) revised; (a)(2)(iv) and (7) added 21561

422.53 Added 21561

422.62 (a)(2)(i), (iii) and (5) revised; (a)(2)(iv) and (7) added 21561

422.68 (f) added 21562

422.74 (d)(1)(v) and (vi) added 21562

422.100 (j) and (k) added 21562

422.101 (d)(2) and (3) revised; (f)(2)(vi) added 21562

(f)(1)(ii) amended; eff. 10–31–11 54634

422.106 (d)(1) revised; (d)(4), (5) and (6) added 21562

422.107 (d)(1)(ii) revised 21563

422.111 (b)(12) and (h) added; (f)(12) removed 21563

422.112 (a)(10) introductory text revised 21563

422.113 (b)(2)(v) revised 21563

422.152 (g) introductory text revised 21564

422.153 Revised 26546

422.156 (b)(1) revised 21564

422.214 (c) and (d) added 21564

422.252 Amended 21564

422.254 (a)(5) added 21564

422.256 (a) introductory text revised 21564

422.258 (a)(1) and (2) revised; (c)(3)(i) amended; (d) added 21564

422.260 Added 21566

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422.266 (a) revised 21567
422.308 (c)(4), (5) and (6) added 21567
422.458 (f) removed 21568
422.502 (b) redesignated as (b)(1); (b)(2) added; (c)(2)(i) revised 21568
422.504 (a)(14) redesignated as (a)(16); new (a)(14), (15) and (n) added; new (a)(16) revised 21568
422.506 (a)(5) added 21568
422.508 (d) added 21569
422.512 (e) redesignated as (e)(1); (e)(2) added 21569
422.562 (a)(4) added 21569
422.564 Regulation at 68 FR 16667 confirmed 21560
422.566 (d) added 21569
422.622 (g)(1) revised 21569
422.624 Regulation at 68 FR 16667 confirmed 21560
422.626 Regulation at 68 FR 16667 confirmed 21560
(g)(3) revised 21569
422.2264 (e) revised 21569
422.2268 (g) and (h) revised; eff. 10–31–11 54634
422.2272 (e) added 21569
422.2274 Introductory text, (b) and (c) revised 21569
(a)(1)(ii) introductory text, (B), (iv) and (4) revised; eff. 10–31–11 54634
423.4 Amended 21570
423.34 (c) and (d)(1) revised; (d)(4) added 21570
423.38 (b) revised; (d) added 21570
423.40 (d) added 21570
423.44 Heading revised; (d)(1)(vi), (vii) and (e) added 21570
423.100 Amended 21571
423.104 (d)(5)(iii)(B) redesignated as (d)(5)(iii)(F); new (d)(5)(iii)(B) through (E) and (v) added; (d)(2)(i) introductory text, (ii), (3) introductory text, (4) and new (5)(iii)(F) revised 21571
423.120 (b)(3)(iii)(B) and (iv) revised; (d) added 21572
423.128 (b)(7) revised; (d)(1)(iii) and (iv) added 21573
423.150 (b) through (g) redesignated as (c) through (h); new (b) added 21573
423.153 (d)(1)(vii)(B) revised; (d)(1)(vii)(D) added 21573
423.154 Added 21573

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423.265 (b)(3) added 21573
423.272 (b)(4) added 21574
423.286 (a) revised; (d)(4) added 21574
423.293 (d) and (e) redesignated as (e) and (f); new (d) added 21574
423.464 (f)(2) revised 21574
423.503 (b) redesignated as (b)(1); (b)(2) added; (c)(2)(i) revised 21574
423.505 (b)(22), (23) and (o) added 21574
(b)(21) introductory text revised; eff. 10–31–11 54634
423.507 (a)(4) redesignated as (a)(5); new (a)(4) added 21575
423.508 (f) added 21575
423.509 (e) added 21575
423.510 (e) redesignated as (e)(1); (e)(2) added 21575
423.520 (c)(2)(ii), (3) and (e)(2) revised; eff. 10–31–11 54634
423.562 (a)(1)(ii) and (iii) redesignated as (a)(1)(iii) and (iv); new (a)(1)(iii) and (5) added; (a)(3) revised 21575
423.566 (d) added 21576
423.568 (f) revised 21576
423.772 Amended 21576
423.780 (b)(2)(ii)(C) revised; (f) added 21576
423.782 (a)(2)(ii) revised 21576
423.884 (c)(3)(ii) and (iii) redesignated as (c)(3)(iii) and (iv); new (c)(3)(ii) added; (d) introductory text, (1)(i), (ii) and (5)(iii)(C) revised 21576
423.2264 (e) revised 21577
423.2268 (g) and (h) revised; eff. 10–31–11 54634
423.2272 (e) added 21577
423.2274 Introductory text, (b) and (v) revised 21577
(a)(1)(ii) introductory text, (B), (iv) and (4) revised; eff. 10–31–11 54635
424 Technical correction 1670
424.22 (b)(1)(i) and (ii) correctly added 9503
(a)(1)(v) introductory text and (A) revised 68606
424.57 (e) revised 5962
424.502 Amended 5962
424.514 Added 5962
424.515 (e) added 5963
424.518 Added 5963
424.525 (a) introductory text revised; (a)(3) added 5964

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424.530 (a)(9) and (10) added 5964
424.535 (a)(6) and (c) revised; (a)(12) added 5964
424.570 Added 5965
425 Added 67973

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414 Technical correction 227
415 Technical correction 227
416 Technical correction 227, 24409
416.44 (a)(3) removed; (c) revised 29030
416.171 (b) introductory text correctly revised 227
417.422 (d) revised 22166
417.427 Added 22166
417.432 (d) revised 22166
417.460 (c)(3) and (4) added 22166
417.492 (a)(1)(i) and (ii) amended; (a)(1)(iii) and (b)(1)(iii) removed 22166
417.801 (d)(1)(ii) revised 22166
419 Technical correction 227, 24409
422.60 (c)(1) amended 22166
422.100 (l) added 22166
422.101 (d)(1) revised 22167
422.102 (e) added 22167
422.111 (i) added 22167
422.216 (d)(1) revised 22167
422.500 (a) revised 22167
422.501 (a) and (e) revised; (c)(1)(i) amended; (c)(1)(iii) added 22167
422.502 (a)(1), (b)(1) and (c) introductory text amended; (b)(3) and (4) added; (c)(2) and (3)(i) revised 22167
422.504 (a)(17) and (18) added; (i)(3)(iii), (4)(i), (ii), (iii), (iv) introductory text and (5) revised 22168
422.510 (a)(14) added 22168
422.641 (d) added 22168
422.660 (a)(5) and (b)(5) added 22168
422.2274 (a)(1)(i) and (iii) revised; (a)(1)(ii) removed; (f) added 22168
423.56 (a) and (f)(3) revised 22168
423.100 Amended 22169

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Correctly amended 32407
423.104 (h) and (i) added 22169
423.120 (c)(5) added 22169
423.153 (b) introductory text, (1) and (2) amended; (b)(4) added; (d)(1)(vii)(B) revised 22169
423.160 (b)(3)(i), (ii), (c)(1)(iii) and (2)(i) revised 29030
423.454 Amended 1882
423.458 (c)(1) revised; (c)(2) redesignated as (c)(3); new (c)(2) added 1882
(c)(4) added 22170
423.501 Amended 22170
423.503 (b)(1) amended; (b)(3) and (4) added 22170
423.505 (b)(24), (25) and (26) added; (i)(3) introductory text, (iii), (v) and (4)(i) through (iv) added 22170
423.509 (a)(13) added 22170
423.514 (d) through (g) redesignated as (g) through (j); new (d), (e) and (f) added 22171
423.600 (a), (b) and (c) revised 22171
423.602 (a) revised 22171
423.882 Amended 1883
423.1000 (a)(3) added 22171
423.1002 Amended 22171
423.2274 (a)(1)(i) and (iii) revised; (a)(1)(ii) removed; (f) added 22171
423.2300—423.2345 (Subpart W) Added 22172
424.30 Revised 53682
424.57 (a) and (c)(30)(ii)(B) amended; (c)(1)(ii), (7)(i)(A) and (11) revised; (c)(1)(iii) removed 14994
424.506 Regulation at 75 FR 24448 confirmed; (b) and (c)(1) revised 25317
424.507 Regulation at 75 FR 24448 confirmed; revised 25317
424.510 (a) revised 29030
424.516 Regulation at 75 FR 24449 confirmed 25317
(f)(1) and (2) revised 25318
424.535 Regulation at 75 FR 24449 confirmed 25317
(a)(10)(i) amended 25318
(c) revised 29030
424.540 (a) introductory text and (2) revised; (a)(3) added 29030